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## (54) Artificial ventilation system

(57) An artificial ventilation system and a method for controlling the artificial ventilation system for obtaining an optimized artificial ventilation of a lung system of a patient is described. Optimal artificial ventilation is obtained when the blood system of the patient is maximally oxygenated and, at the same time, the negative influence on the cardio-pulmonary system is minimized. The ventilation system comprises a gas delivery unit (2) for delivering controllable inspiration pulses to a patient (4), a monitoring unit (14) for measuring at least one parameter related to the function of the lung system, such as a blood gas analyser, and a control unit for determining an optimal peak inspiratory pressure and pressure amplitude for the inspiration pulse based on the measured blood gas parameter.

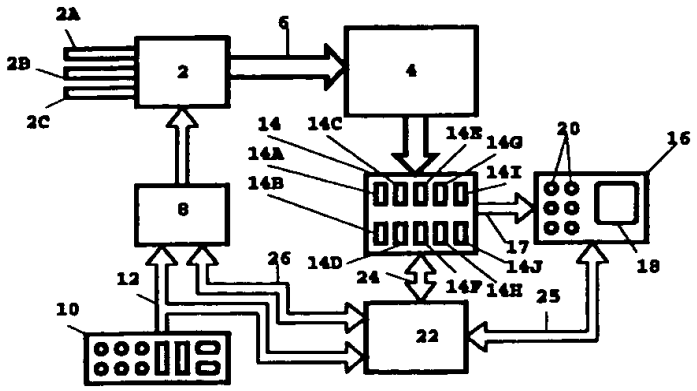


FIG 1

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## Description

The present invention relates to an artificial ventilation system comprising a respiratory gas delivery unit, connectable to a lung system for delivering controllable inspiration pulses of respiratory gas to the lung system, a regulating unit operatively connected to the respiratory gas delivery unit for controlling the inspiration pulses based on a control signal supplied to the regulating unit, a monitoring unit for measuring at least one parameter related to the function of the lung system and a control unit connected to the monitoring unit for determining a change in an inspiration pulse parameter.

The present invention also relates to a method for controlling an artificial ventilation system.

It should be noted that, in relation to this application, the term inspiration pulse includes all relevant parameters which in any way defines the inspiration pulse and its effect on a lung system. For example, the positive end expiratory pressure (PEEP) is normally set as an external overpressure on the lungs at the end of each expiration. However, the following inspiration pulse will commence at this elevated pressure and the effect of the inspiration pulse on the lungs is also dependent on PEEP. PEEP is therefore also a relevant parameter for the inspiration pulse. The same reasoning is valid when regarding expiration time, since the effect of a particular inspiration pulse is also dependent on, inter alia, the ratio between inspiration time and expiration time.

The lungs are one of the most important organs in a living being. The main function of the lungs is the gas exchange between the organism and the environment. Oxygen ($O_2$) in the air is diffused into the blood system and carbon dioxide ($CO_2$) diffuses from the blood system to the air in the lungs. The $CO_2$ is then removed from the lungs during expiration. The actual exchange of gas takes place in the air/fluid interface in the alveoli. There are about 300 million alveoli in a healthy human lung system, having a total area of about 100 $m^2$. The alveoli are enmeshed in the pulmonary capillary network, which forms a fine network of minute capillaries. The capillaries are so thin, that only one red blood cell at a time can pass through.

As a result of injuries or disease or even due to artificial ventilation (such as during anaesthesia), the function of the lung can be effected to such a degree, that the patient (normally a human being or a domestic animal) cannot maintain a sufficient spontaneous respiration. Artificial respiration, or ventilation, must then be provided. The simplest and fastest way of providing artificial respiration in acute situations is mouth-to-mouth respiration. This is, however, not sufficient for prolonged treatment, nor for all kinds of acute illnesses.

Mechanical artificial respiration has been known for a long time, for instance by the so called iron lung. The iron lung comprises a chamber which covers the patient up to the neck. To force the patient to inhale, air is pumped out of the chamber, thereby forcing the chest to expand. Air will then flow down into the lungs. The bulky chamber and the problem of having the patient's body completely encased, are major disadvantages for this kind of artificial respiration, which usually is referred to as negative pressure respiration.

During the polio epidemic in the 1950's a large number of patients were suddenly in great need for artificial respiration. Positive pressure respiration was then developed. In principal a piston pump was used for creating an overpressure which, via a tube and a breathing mask, forced air into the patient's lungs. The pumps were at the beginning manually controlled, normally by students, who regularly pumped air into the patients lungs. Mechanic driving mechanisms for the pump were then developed.

Most of these first positive pressure ventilation systems controlled the tidal volume ($V_t$) of the patient, as they forced a defined volume, i.e. the pump's stroke volume, into the patient's lungs during each inspiration. As long as the lungs have a good compliance, this causes no problem. But when there are atelectatic regions, i.e. the lung is "stiff", the supplied volume can cause pressures within the lungs which harm the lung. The pressure difference between different regions of the lung may give rise to shear forces, which damage the lungs and prolong the recovery of the patient. A high absolute pressure may cause neighbouring alveoli to compress an interjacent capillary and prevent the vital blood flow (overdistension). In severe cases, excessive pressure may even cause tissue rupture.

Since then, artificial ventilation systems have been greatly improved. In the 60's, electronically controlled ventilators were developed, which could control pressure and flows with higher accuracy than the preceding mechanic ventilators. Several new ventilation modes were developed, as well.

In a modern state of the art ventilator system, such as the Servo Ventilator 300, Siemens-Elema AB, Sweden, the physician may select among a vast number of ventilation modes, such as pressure control (PC), pressure support (PS), volume control (VC), volume support (VS), pressure regulated volume control (PRVC), continuous positive airway pressure (CPAP), synchronized intermittent mandatory ventilation (SIMV), and others, including variations of the mentioned modes. It is also possible to use one and the same ventilator for neonate, paediatric and adult patients.

However, only providing respiratory air to a patient's lungs is not sufficient. Since all lung systems are individual and may for instance display different compliance and more or less atelectatic regions, any treatment must be adapted to the specific patient. In particular, when using positive pressure ventilation, care must be taken not to supply too high pressures or volumes of respiratory gas, since these can cause barotrauma and volutrauma. As already mentioned, overdistension and even tissue rupture within the lungs may be caused by extreme peak pressures. Another risks is depletion of surfactant in the alveoli, due to large tidal volumes ($V_t$) and pressure changes, end expiratory lung volume less

than the lung's functional residual capacity (FRC), as well as repeated transgressions from closed to open state. The depletion of surfactant causes the lung to stiffen. As the patient's condition changes (improves or deteriorates), the treatment must also change. Another mode could be selected or a change could be made in one of the numerous parameters related to the inspiration pulse. The importance of monitoring the condition of the patient was therefore realised at an early stage and this area has also been developed.

Lung mechanics were probably the first factor to be considered by physicians when determining how to treat a certain patient. By using spirometers combined with other instruments some lung mechanic parameters, such as tidal volume, residual volume and functional residual capacity (FRC), could be determined. Resistance and compliance have also been determined for lungs, by different measurement and calculation methods. These parameters could be used by the physician to determine the condition of the lungs. Another factor which had to be taken into consideration was the dead space. For the normal lung system the mouth, nose, pharynx, trachea and bronchi comprise the anatomic dead space. In addition to this, the tubing connecting the ventilation system to the patient adds to the dead space, thereby increasing rebreathing of exhaled $CO_2$-enriched gas. Thus, the $CO_2$ also had to be considered in order to improve ventilation of the lung system and, in particular to avoid hypoventilation (resulting in a too high blood $CO_2$ level) and hyperventilation (resulting in a too low blood $CO_2$ level).

Apart from these additional considerations, general monitoring of the condition of the patient has become an important tool, especially in intensive care. Normally, monitoring can include measurement of ECG, EEG, $CO_2$, oxygen saturation ($S_aO_2$) and, more recently, partial pressure of oxygen ($P_aO_2$) and carbon dioxide ($P_aCO_2$) in the blood. The experienced physician will then try to ventilate the patient in order to obtain certain life supporting values of these monitored parameters, such as a sufficient oxygen saturation.

For some inspiration pulse parameters, closed loop systems have been described, where a measured body function parameter is utilized in a control system for automatically changing the inspiration pulse parameter. In a ventilator system described in US-A-5,103,814, the measured $S_aO_2$ of the patient is used for controlling the percentage of oxygen in a respiratory gas. In other words, if the $S_aO_2$ is below a threshold value, a higher percentage of oxygen ($F_iO$) will be supplied to the patient and if the $S_aO_2$ is higher than the threshold value, the $F_iO$ in the respiratory gas will be reduced. A similar system is described in EP-A-504 725. One major problem for these systems is: changing one parameter is not sufficient. For instance, if the lungs suddenly collapse, even an increase to 100% $O_2$ is not sufficient have an optimal gas exchange.

Other attempts of automation have also been made. In an article entitled "Automatic weaning from mechanical ventilation using an adaptive lung ventilation controller", Linton et. al., Chest 1994 Dec.; 106(6): 1843-1850, a system for automatic weaning of a patient is described. The described system was automatically adapted to the lung mechanics of the patient on a breath to breath basis and aimed to minimize work of breathing, to maintain alveolar ventilation and to prevent intrinsic PEEP. In US-A-4,986,268 a more complete control is aimed at. Oxygen and carbon dioxide contents in expired air are measured and based on these, together with predetermined lung elastance and air viscosity factors, the tidal volume ($V_t$) and respiratory rate (RR) are automatically calculated and set. Yet another system is described in an article entitled "An adaptive lung ventilation controller", by Laubscher et. al., IEEE Trans. Biomed. Eng. 1994 Jan; 41(1):51-59. In this system the physician programs a desired gross alveolar ventilation and the control system tries to maintain this desired level by automatically adjusting the mechanical rate and inspiratory pressure level. The adjustments are based on measurements of the patient's lung mechanics and series dead space.

Although these systems may provide automated system solutions for certain functions, or a certain category of patients, they do not succeed in presenting full automatic control of a patient's breathing, irrespective of the condition of the patient and most do not aim at accelerating the recovery time.

All in all, there are many parameters and factors to consider when deciding how to apply the best possible artificial ventilation on a specific patient. Many parameters relating to the condition of the patient and/or the lung system have been found, but the interconnection between the parameters and how they should be utilized for optimum treatment has not been seen. Problems which can arise are insufficient oxygenation, hypoventilation, hyperventilation, volutrauma, barotrauma, overdistension, tissue rupture, shear forces, etc. In particular, although it has always been the purpose of obtaining an optimal artificial ventilation for a patient, such a system has never been realized.

It is an object of the invention to achieve an artificial ventilation system which obtains an optimal artificial ventilation for a patient, considering the most relevant parameters for the condition of the patient and aiming at an improved recovery time for the patient and the lung system.

It is also an object of the invention to achieve a method for controlling an artificial ventilation system in such way.

The object is achieved by the invention in that the artificial ventilation system is devised according to the characterizing portion of claim 1.

Basically, it has now been recognized that the vital importance of artificial ventilation is to reduce the pressure load on the lung system and at the same time achieve a sufficient oxygenation of the blood system. This will provide a life sustaining condition, with a minimum of negative effects for the patient.

In principle, the basic characteristics of the alveoli have to be taken into account. The alveoli can be described with reference to the LaPlace law, i.e. $P = 2\gamma/r$, where P is a pressure required to sustain a particular radius of a bubble, $\gamma$ is the surface tension of the fluid gas interface and r is the radius of the bubble. A collapsed alveolus requires a relatively high pressure in order to begin to inflate, but as the radius increases when the alveolus expands, the pressure required for further inflation is reduced. In other words, when the alveoli are inflated, they will not require a high pressure to remain open. The importance of maintaining the lung open is described in more detail in an article entitled "Open up the lung and keep the lung open", Intensive Care Medicine, 1992, 18:319-321. The artificial ventilation system of the present invention takes advantage of this characteristic, extrapolated onto the whole lung, and combines it with a vital life supporting parameter, the oxygenation of the blood system.

By minimizing the pressures supplied to the lung, in particular peak pressure and pressure amplitude, the negative effects of the cardio-pulmonary system, such as barotrauma, volutrauma, overdistension and hypoxic vasoconstriction can be minimized, if not completely avoided. The artificial ventilation system operates most efficiently in the pressure control mode, when the patient does not breathe spontaneously, and in support modes, when the patient breathes spontaneously. However, other modes of operation are possible to apply with the same advantageous results. For instance, in volume control mode the pressure could be measured and the supply of respiratory gas could be controlled so that the desired pressure parameters are obtained and maintained.

Several advantageous improvements of the artificial ventilation system are described in the dependent claim.

For instance, the blood gas parameter which is preferably utilized is the partial pressure of oxygen ($P_aO_2$). The $P_aO_2$ is the best blood gas parameter, which reflects the oxygenation of the blood system. $P_aO_2$ is better than, for instance, saturation of oxygen in blood ($S_aO_2$) or by calculating arterial oxygenation by measuring expired oxygen content. This because $P_aO_2$ varies even when the blood is fully saturated.

The system can operate completely automatic, since all relevant parameters can be measured automatically on site. As will be described below, other operations are also possible.

The invention also relates to a method for controlling the artificial ventilation system in order to obtain the optimum ventilation. The inventive method is described in independent claim 18 and improvements of the method are described in the dependent claims to this claim.

In one embodiment of the invention, the expiration flow is measured in a flow meter and optimal settings for inspiration/expiration time ratio (I:E ratio) and respiration rate (RR) are determined based on the quotient between a determined end expiratory flow ($\Phi_{EE}$) and a peak expiratory flow($\Phi_{PE}$).

In another embodiment of the invention, a monitor screen is connected to the monitoring unit for displaying measured parameters. The monitor screen could also be connected to the control unit for displaying determined inspiration pulse parameters. Using a monitor screen provides a perfect interface between the artificial ventilation system and a physician. The physician can select whether the artificial ventilation system should operate automatically and control the entire ventilation of the patient itself, or if the control unit should only display the suggested new parameters on the screen, whereupon the physician decides whether or not to use the suggested parameters for the treatment or diagnosis of the patient. The monitor screen and monitoring unit may be parts of a total monitoring system for the patient. For instance, in intensive care, monitoring of ECG, EEG, haemodynamic parameters, such as blood pressures, oxygen saturation, partial pressure of oxygen and carbon dioxide in the blood, oxygen consumption, carbon dioxide production and other parameters can be measured and displayed on the monitor screen.

In all, this provides a ventilation system which has a great potential for all artificial ventilation. In hospitals, the ventilator system may even be utilized as an education tool for the staff. The interface operation via the monitor screen presents at all stages information of the patients condition and how to ventilate the patient in each instance.

In a further embodiment of the invention the condition of the lungs is first determined by checking whether the lungs are collapsed or not. This is reflected in the partial pressure of oxygen in the blood. If the lungs are collapsed, an opening pressure procedure will be activated. When an opening pressure ($P_o$) has been determined, a closing pressure ($P_c$) of the lung system will also be determined. The closing pressure ($P_c$) will then reflect the lowest pressure, at which the lungs may be ventilated to provide for a sufficient oxygenation of the blood.

The method for controlling the artificial ventilation system is preferably comprised in a number of logical rules, or protocols. By evaluating the condition of the lungs at predetermined intervals, a defined set of rules, or a particular protocol, can be activated when necessary. In particular, the present invention includes an opening protocol, a reduction protocol, a maintenance protocol and a weaning protocol. The opening protocol provides for the determination of the opening pressure ($P_o$). The reduction protocol provides for the determining of the closing pressure ($P_c$). The maintenance protocol aims to keep the lungs open. And the weaning protocol, finally, is activated when the patient has improved enough to be weaned from the artificial ventilation. Since these protocols follow the condition of the patient, they will normally always follow in the same consecutive order: opening protocol, reduction protocol, maintenance protocol and weaning protocol.

In the following, embodiments of the invention will be described in more detail, referring to the figures, in which

FIG. 1 schematically shows an embodiment of the artificial ventilation system,
FIG. 2 illustrates the basic idea for a concept of optimizing the ventilation of a lung system,
FIG. 3 shows a pressure volume diagram, illustrating the behaviour of a collapsed lung,
FIG. 4 shows a first flow chart describing a first method of controlling the ventilator system,
FIG. 5 shows a second flow chart illustrating a second method for controlling the ventilator system,
FIG. 6 shows a pressure diagram and a flow diagram for an inspiration pulse,
FIG. 7 illustrates in a flow chart a first series of substeps for the second method,
FIG. 8 illustrates in a flow chart a second series of sub-steps for the second method,
FIG. 9 shows a series of inspiration pulses for determining an opening pressure,
FIG. 10 illustrates in a flow chart a third series of sub-steps for the second method,
FIG. 11 shows a sequence of inspiration pulses for determining a closing pressure,
FIG. 12 illustrates in a flow chart a fourth series of sub-steps for the second method,
FIG. 13 illustrates in a flow chart a fifth series of sub-steps for the second method,
FIG. 14 illustrates in a flow chart a sixth series of sub-steps for the second method,
FIG. 15 illustrates in a flow chart a seventh series of sub-steps for the second method,
FIG. 16 shows a respiratory gas delivery system, which can be used for the artificial ventilation system, and
FIG. 17 illustrates in a flow chart an eighth series of substeps for the second method.

The artificial ventilation system comprises a gas delivery unit 2, which receives controllable amounts of gas via gas inlets 2A, 2B, 2C. The received gases are mixed in predetermined fractions within the gas delivery unit 2 and are then delivered to the lung system of a patient 4, via a gas delivery system 6. Respiratory gas can be delivered intermittently, during inspiration phases or constantly, whereby an inspiration pulse of respiratory gas is superimposed during the inspiratory phase. The gas delivery unit 2 is regulated by a regulating unit 8, which regulates the flow, pressure, gas mix, timing, etc. of the respiratory gas. All these inspiration pulse parameters can be entered on a control panel 10 by a physician or other clinical staff, whereby a control signal is transferred from the control panel 10 to the regulating unit 8 via a databus 12. The control panel 10 can also be equipped with the possibility of entering patient information such as age, sex and body weight or size, which may be used for further optimization of the treatment. Other possible information which can be entered to have an impact on the system are, the reason for the artificial respiration (illness, insufficient respiration, insufficient respiratory muscles, etc.), and information regarding the physical condition of the patient (cyanosis, chest wall movements, emphysema, skin temperature, etc.).

The patient 4 is also connected to a monitoring unit 14. The monitoring unit 14 comprises a blood gas analyser 14A, which is connected to the blood system of the patient 4, a flow meter 14B for measuring respiratory gas flow to and from the lung system of the patient 4, a pressure gauge 14C for measuring the pressure in or near the lung system of the patient 4, a blood pressure meter 14D for measuring the blood pressure of the blood system of the patient 4 and a $CO_2$-meter 14E for measuring the carbon dioxide content in the expired respiratory gas.

Other components of the measuring unit can be an oxygen meter 14G, a lung mechanics meter 14H, an electrocardiograph 14I and an electroencephalograph 14J. Meters for body temperature and other parameters reflecting the patient's condition can also be included in the measuring unit 14.

All measured parameters can be transferred to a monitor screen 16 via a databus 17. In the monitor screen 16, graphs or values can be displayed on a display 18. A physician can select which parameters to view via control knobs 20. The monitor screen 16 may also be equipped with the possibility of entering patient data, as described above for the control panel 10. The monitoring unit 14 is also connected to a control unit 22 via a databus 24. The control unit 22 is further connected to the control panel 10 via the databus 12 and receives from the control panel 10 the set inspiration pulse parameters, as well as the selected ventilation mode and the type of patient, i.e. whether the patient is neonatal, paediatric or adult. It can, thus, also receive information about the patient's weight or size, age and sex, all entered on the control panel 10 or on the monitor screen 16. On the basis of the measured parameters from the monitoring unit 14 and the current settings on the control panel 10 and monitor screen 16, the control unit 22 will calculate and determine an optimal new setting for the artificial ventilation system and in particular an optimal setting for the inspiration pulse, such as peak inspiratory pressure (PIP), end pressure, positive (PEEP) or negative (NEEP), respiration rate (RR) and inspiration/expiration time ratio(I:E ratio).

The control unit 22 can also calculate parameters related to the measured parameters in the monitoring unit 14 and these calculated parameters can also be displayed on the monitor screen 16. Calculated parameters are, for instance, tidal volume, minute volume, oxygen consumption, $CO_2$ tidal production and $CO_2$ minute production. These calculated parameters can also be utilized for calculation of new settings. The change in certain parameters over time, such as blood gases, oxygen consumption, etc., can also be deter-

mined by the control unit 22 and utilized for determining new settings.

It should be noted that the blocks in FIG. 1 refer to function more than physical construction. In other words, some of the meters in the monitoring unit 14 (e.g. the flow meter 14B and the pressure gauge 14C), as well as the regulating unit 8, may be integrated with the gas delivery unit 2, whereas other meters in the monitoring unit 14, such as the blood gas analyser 14A, can consist of a separate apparatus. Likewise, the control unit 22 and the monitor screen 16 can be integrated parts of a computer, such as a PC.

The determining of new settings can be based on an iterative method, where settings are altered one at a time and the outcome of the change is monitored via the monitoring unit 14 before further changes in the settings are made. The determining can also be based on a pure mathematical calculation based on current patient data and patient data collected in a database for providing a knowledge background for the control unit 22. The database comprising the knowledge background is very useful when deciding maximum values and threshold values for both the measured parameters and the set inspiration pulse parameters.

The determined new settings can be displayed on the monitor screen 16. The displayed setting can then be regarded as a suggestion of a new setting and the physician may choose to change the setting accordingly or not. The display may also be made as an information of the next automatic setting for the ventilation system. In this case, the control unit 22 generates a further control signal, which is transferred to the regulating unit 8 via a databus 26. The further control signal will in this case override the control signal from the control panel 10. Preferably the physician may select whether the system should be completely automatic (closed loop ventilation), semi-automatic or manual.

In order to be able to determine an optimal setting, the control unit 22 comprises a set of determining protocols or control methods. In FIG. 2 a basic set of such protocols is illustrated. As the patient is connected to the ventilation system an evaluation (28) of the patient's condition is made and depending on the status of the condition, different protocols are activated by the control unit 22. Therefore, if the lung system of the patient 4 has collapsed, an opening protocol 30 will be activated, which opening protocol 30 will be described in greater detail below. If the lungs are sufficiently open a reduction protocol 32 is activated, which reduction protocol 32 is also described in further detail below. The reduction protocol 32 is mainly aimed at finding the lowest peak pressure PIP and pressure amplitude, at which the lungs remain sufficiently open. Next, a maintenance protocol 34 will be activated to keep the lung open at lowest possible pressure, but with maintained sufficient oxygenation of the blood. Finally, if the patient basically is healthy but, due to the artificial ventilation of the lung system, the respiratory muscles has become weaker or the patient has become used to the artificial ventilation, a weaning protocol 36 is activated, which also will be described in greater detail below. Normally, these protocols always follows in the same sequence: opening, reduction, maintenance and weaning.

The present artificial ventilation system is basically based on the concept of providing a sufficient oxygenation of the blood system with a minimum of negative effects on the cardio-pulmonary system. In order to achieve this, the basic function of the lungs, and in particular the alveoli, must be considered. In FIG. 3 this is illustrated in a volume pressure diagram. In the diagram a curve 35 is drawn to illustrate the relation between volume and pressure in a collapsed alveolus. In a first region 35A of the curve 35, the pressure will increase rapidly whereas the volume only increases slowly. The reason for this was explained above, relating to the LaPlace law. A high pressure is required in order to open up the alveolus. As the alveolus begin to inflate, the volume increases, second region 35B, more rapidly. At one point 35C, the curve 35 turns. This point is referred to as the opening pressure $P_{oa}$ of the alveolus. The alveolus will then expand, thereby causing an increase in volume at lower distension pressures. This continues all through a third region 35D, until an equilibrium is reached. At this equilibrium is a second turning point 35E. Further expansion of the alveolus will, due to the retroactive force of the tissue, require an increase in pressure. This relationship is maintained up to a fourth region 35F. Here the alveolus is so inflated, that the chest physically hinders further expansion. Any increase in pressure at this stage can cause lung tissue damage and depression of the cardio-vascular system. In the diagram the closing pressure $P_c$ and ideal peak inspiratory pressure PIP and positive end expiratory pressure PEEP have been indicated. The difference between PIP and PEEP is the pressure amplitude $\Delta P$ for the inspiration pulse. This relation is then extrapolated on the whole lung.

A first method for realizing the logical sets of rules, or protocols, is shown in FIG. 4. The depicted flow chart illustrates the different steps which have to be taken, in order to obtain the optimal oxygenation. It could here be suiting to first explain some further principles behind the optimum artificial ventilation of a patient, in addition to those explained in connection with FIG. 3. The idea is to provide sufficient alveolar ventilation, i.e. supply oxygen and remove carbon dioxide. This is, however, not sufficient. Preferably, only air should be used (i.e. a low inspired oxygen concentration) and any damage on the cardio-pulmonary system must be minimized. Oxygenation of blood is controlled by measuring partial pressure of oxygen ($P_aO_2$) instead of, for instance, saturation of oxygen ($S_aO_2$). $P_aO_2$ is preferred since it reflects gas exchange even at 100% $S_aO_2$. Further, pressures, in particular peak inspiratory pressure, PIP, and pressure amplitude of the inspiration pulse, should be as low as possible, since they will then cause least physical harm to the lungs and the cardiovascular system. Since respiratory rate (RR) and inspiration/expiration time ratio (I:E

ratio) can effect the pressure within the lungs at the end of expiration, so called intrinsic positive end expiratory pressure (intrinsic PEEP or $PEEP_i$), these are also varied in order to optimize them.

For most patients, PIP, PEEP (PIP-PEEP = pressure amplitude), RR and I:E ratio can be optimized by relatively simple means, thanks to the insights obtained by the invention. $P_aO_2$, blood pressure and expiration flow $\Phi_E$ are the necessary measured parameters. The realization of the importance of and connection between these parameters has made real closed loop ventilation possible.

Returning to FIG. 4, in the first block 38 the entire procedure begins. In the second block 40, measurements of the partial pressure of oxygen $P_aO_2$ and the ventilatory condition, such as respiratory rate RR, are read by the control unit. A determination whether the lung is sufficiently open or not is then performed, block 42. This determination is in this case basically based on the measured $P_aO_2$. If the measured $P_aO_2$ is lower than a predetermined threshold value, the lungs are determined not to be open. If this is the case, output No in block 42, the opening protocol in block 44 is activated. In the opening protocol procedure, the lungs are opened up and the oxygenation of the blood will thus improve. New settings may be required. Further measurement of $P_aO_2$ and reading of settings are then performed again in block 40, before a further test of the condition of the lung is made in block 46.

At this stage it is checked whether a closing pressure $P_c$ has been determined. If not, output No in block 46, the reduction protocol, block 48 will be activated. When the reduction protocol has been run through, the measurements and readings of block 40 are performed again. During the reduction protocol procedure it is determined whether new settings are preferable and whether there is hypoventilation or hyperventilation present.

When the closing pressure $P_c$ has been determined, output Yes in block 46, the maintenance and weaning protocol is activated in block 50. The maintenance and weaning protocol procedure is made to keep the lung open and, finally, wean the patient from the dependency of the artificial ventilation. In block 52, which follows the maintenance and weaning protocol, there is a test whether or not the weaning has been successful. If not, output No in block 52, the measurements and readings of block 40 are performed again. If, on the other hand, the weaning has been successful, output Yes in block 52, the treatment is at an end, block 54, and the patient can be disconnected from the artificial ventilation system.

Referring now to FIG. 5 - 17 a second method for obtaining an optimal ventilation of a patient's lung system is described.

The different protocols will also be described in more detail in connection with the second method.

In FIG. 5 a flow chart illustrates the overall basis of the second method. The procedure begins with start block 56 and proceeds in block 58 with an attempt to find an optimal ratio between inspiration time and expiration time (I:E ratio). As long as it has not been found, output No in block 60, it will continue this procedure. When the optimum I:E ratio has been found, output Yes in block 60, an optimal respiratory rate (RR) is sought, block 62. As with the I:E ratio, the procedure of finding the optimal respiratory rate (RR) will continue as long as the optimal RR has not been found. When the optimal RR is determined, output Yes in block 64, the second method proceeds, block 66, by finding the opening pressure $P_o$. As with the previous determinations, a loop will continue between block 68 and block 66 until the opening pressure $P_o$ is found. Blocks 66 and 68 thus correspond to the opening protocol mentioned above. In some cases a "true" opening pressure $P_o$ will not be found (mainly due to very severe conditions of the lung). The second method then proceeds with the reduction protocol, which begins in block 70 by finding the closing pressure $P_c$. The closing pressure $P_c$ is basically the pressure at which the lungs will begin to collapse again, after having been opened up. In block 72, this test is performed until the closing pressure $P_c$ has been found. The found opening and closing pressures ($P_o$, $P_c$) are then set sequentially and the lungs are maintained open according to the maintenance protocol in block 74. The second method is concluded in block 76, with the weaning of the patient.

In FIG. 6 two diagrams are shown. The first shows pressure in relation to time for an inspiration pulse 78. The inspiration pulse 78 has a low pressure on PEEP level and a peak pressure of PIP. The pulse 78 has an inspiration phase which lasts during the inspiration time $t_i$ and expiration phase which lasts during the expiration time $t_e$. Below the pressure-time diagram a flow-time diagram depicts the flow to and from the patient during inspiration and expiration. The flow curve 80 begins with a sharp increase up to a maximum inspiration flow $\Phi_{PI}$ and an end inspiratory flow $\Phi_{EI}$. The end inspiration flow $\Phi_{EI}$ should always be zero (0). The tidal volumes will then have had time to be redistributed within the lung. During expiration, a high flow is established at first, the peak expiratory flow $\Phi_{PE}$ since the pressure difference in the lungs and the ambient surroundings are high. At the end of the expiration, the end expiratory flow $\Phi_{EE}$ is measured. The end expiratory flow, $\Phi_{EE}$, is larger than zero if a new inspiration pulse commences before the pressure difference between gas in the lungs and the ambient surrounding (tubing) has been equalized. Based on the peak expiratory flow $\Phi_{PE}$ and the end expiratory flow $\Phi_{EE}$ a ratio of these can be calculated, i.e. the EEPk-flow. Based on the EEPk-flow, the optimum I:E ratio and optimum RR can be determined, as shown in the flow charts in FIGs. 7 and 8.

The substeps for finding the optimum I:E-ratio in the second method are described in FIG. 7, where the first block 82 is the start block. The mentioned EEPk-flow (EEPk$\Phi$) is then compared with a desired EEPk$\Phi$ value, in this case 40. Since the end expiratory flow $\Phi_{EE}$ is

always smaller than the peak expiratory flow $\Phi_{PE}$, the EEPkΦ is always smaller than 1. The desired value 40 thus refers to the fraction, i.e. either 0.40 or 40%. The desired value, 40, used in this example, can be chosen from any value between 1 and 99, depending on which patient is connected to the ventilation system (i.e. age, size or weight, sex, reason for need of artificial ventilation, etc.). The selection of a good value can be made based on the knowledge database. A preferable interval for the desired EEPkΦ is, however, 30-40. The same is valid for I:E ratio, which usually is referred to as a percentage. If the EEPk-flow exceeds this desired EEPkΦ value, output No in block 84, the optimum I:E ratio for the patient has been found, block 86. If the EEPk-flow is below 40, output Yes in block 84, the I:E ratio is compared with a maximum setting for the I:E ratio, block 88. Similar to the above, the value of the maximum I:E ratio depends on the patient and his/her status. Any percentage between 1 and 99% is possible. Again, the knowledge database would provide a preferable value for the individual patient. In this embodiment, the maximum I:E ratio is 80%. If the I:E ratio already is at the maximum, output No block 88, this I:E ratio is used as the optimal I:E ratio for the time being, since a better value can not be determined due to the patients condition. The sequence is then at an end, block 86.

If, however, the I:E ratio is below maximum, output Yes block 88, the I:E ratio is compared with a first I:E ratio thresh-old value, in this case 67%. If the I:E ratio exceeds 67%, output No block 90, a new I:E ratio is set, block 92, to be equal to the sum of 40 minus EEPk-flow and current I:E ratio. The procedure of determining and comparing the EEPk-flow with the desired EEPkΦ value in block 84 is then repeated. If however the I:E ratio is below 67%, output Yes in block 90, the EEPk-flow is compared to a first EEPkΦ threshold value in block 94. In this second comparison, the threshold value is 15. If the EEPk-flow exceeds 15, output No block 94, a new I:E ratio is set according to block 92. If, however, the EEPk-flow is below 15, output Yes block 94, the I:E ratio is set to the maximum value for the I:E ratio, block 96. The test is then resumed in block 84 by determining and comparing the current EEPk-flow with the first EEPkΦ threshold value.

In a similar way, the flow chart in FIG. 8 illustrates the substeps required for finding the optimal respiratory rate RR. This procedure begins with start block 98 and, as in the evaluation of the optimal I:E ratio, the EEPk-flow is compared with a desired EEPkΦ value, again 40, in block 100. If the EEPk-flow exceeds the desired EEPkΦ value, output No, the optimal respiratory rate RR has been found and the procedure ends in block 102. If, however, the EEPk-flow is below the desired EEPkΦ value, output Yes in block 100, the respiratory rate RR is compared to a maximum value for the respiratory rate RR in block 104. If the respiratory rate RR is already equal to the maximum value for the respiratory rate RR, output No, an optimum respiratory rate RR (for the time being) has been found and the procedure ends in block 102.

If the respiratory rate RR is below the maximum value for the respiratory rate, output Yes block 104, the EEPk-flow value is compared to a second EEPkΦ threshold value, block 106. In this case the second EEPkΦ threshold value is 20. If the EEPk-flow is above 20, output Yes, a new respiratory rate RR is set to 2 times the current respiratory rate RR. If the EEPk-flow is above 20, output No block 106, the EEPk-flow is compared to a third EEPkΦ threshold value, in this case 30, in block 110. If the EEPk-flow is above 30, output No, a new respiratory rate RR is set to 1.2 times the current respiratory rate RR in block 112 and EEPk-flow is then determined and compared again with the first EEPkΦ threshold value of 40, block 100.

If the EEPk-flow does not exceed the third EEPkΦ threshold of 30, output Yes in block 110, a new respiratory rate RR is set to be equal to 1.5 times the respiratory rate in block 114 and the evaluation of EEPk-flow is resumed in block 100.

These evaluation steps for I:E ratio and RR, as described in FIGS. 6 and 7, are then followed by the opening protocol. In FIG. 9 a series of inspiration pulses 116A-116F for determining an opening pressure $P_o$ is shown. The first two inspiration pulses 116A have a positive end expiratory pressure of $PEEP_1$ and a peak inspiratory pressure of $PIP_1$. They have an inspiration time of $t_i$ and an expiration time of $t_e$. The inspiration and expiration times have been evaluated according to the schemes in FIG. 7 and 7 (both I:E ratio and RR effect $t_i$ and $t_e$). If the first inspiratory pulses 116A fails to open up the lungs sufficiently, as indicated by a sufficient $P_aO_2$, a new inspiration pulse or sequence of inspiration pulses 116B is utilized. The second inspiration pulse 116B has an elevated peak pressure $PIP_2$ but the same $PEEP_1$ as the first inspiration pulses 116A. In consecutive steps, the PIP and/or PEEP values will be increased as long as the lungs remain partially closed. The procedure continues either until the lungs open up sufficiently or until maximum settings are reached for PIP and PEEP levels.

The procedure for obtaining the opening pressure $P_o$ and determining the inspiration pulse sequence is described in the flow chart in FIG. 10 where start block 118 indicates the starting point for the opening protocol. The partial pressure of oxygen $P_aO_2$ is first analysed in block 120 (after delivery of a number of inspiration pulses) and the measured $P_aO_2$ is compared with a $P_aO_2$ threshold value for evaluating whether the lung is sufficiently open or not. When the lungs are sufficiently open, output Yes, the procedure has found the opening pressure $P_o$ and the sequence ends in block 124. If the lungs are not sufficiently open, the procedure will instead continue with block 126, where the tidal volume $V_t$ is compared with a $V_t$ threshold of 7 ml/kg. The exemplified threshold value (7 ml/kg) could also be selected from a wider range, 1-20 ml/kg, depending on the patient. Usually, values between 5 and 7 ml/kg are utilized. In other words, if the patient weighs 70 kg in this

case the $V_t$ threshold is 490 ml. The patient's weight is entered on the control panel 10 or the monitor screen 16 as described in connection with FIG. 1. In the alternative, the monitoring unit 14 can be provided with a scales 14F for weighing the patient. Instead of weight, body size could be used for determining the tidal volume. The amount of fat on the patient will then not influence the tidal volume value (amount of fat is not correlated to the size of the lungs).

If the tidal volume $V_t$ is above the $V_t$ threshold, output Yes, hypoventilation is looked for in block 128. Hypoventilation means that the alveoli obtain an insufficient ventilation and the content of carbon dioxide $CO_2$ thus increases in the lungs and the blood system of the patient. If there is no hypoventilation, output No, the intrinsic PEEP is measured and compared with an allowed maximum intrinsic PEEP. If the intrinsic PEEP is below the maximum intrinsic PEEP value, output Yes, the external PEEP is compared with a maximum external PEEP value in block 132. If the external PEEP does not exceed the maximum external PEEP value, output No, a new PEEP is set equal to the current PEEP + 2 $cmH_2O$, block 138. The procedure then resumes at block 120, the $P_aO_2$ analysis. Since it will take some time for the $P_aO_2$ to react on an increase in the gas exchange, due to an increase in the amount of opened up alveoli, one or a few minutes will have to pass before measurement is made.

If the external PEEP, however, is equal to or exceeds the maximum external PEEP value, output No in block 132 an evaluation whether new maxima should be allowed or not is made, block 140. If a new maximum value for PEEP is to be allowed, the procedure resumes in block 120 with the new maximum PEEP value. Likewise, if the intrinsic PEEP is found to be above the maximum $PEEP_1$ value, output No in block 130, it is evaluated, block 140, whether a new maximum value should be allowed.

Going back now to block 126, where the tidal volume $V_t$ was compared with a $V_t$ threshold of 7 ml/kg. If the tidal volume $V_t$ is lower than this the procedure continues with block 142 and compares the current PIP with a maximum PIP value. The maximum PIP value could be any value between 20 and 70 $cmH_2O$, but is preferably between 40 and 60 $cmH_2O$. If the current PIP is lower than the maximum PIP value, output Yes, a new PIP is set equal to previous PIP + 2 $cmH_2O$ and the $P_aO_2$ analysis resumes in block 120. However, should PIP be above the maximum PIP value, output No, it will again be evaluated whether new maxima could be allowed or not in block 140. Otherwise the procedure is at an end, block 124, and the current PIP pressure is the opening pressure $P_o$. In such a case, the lungs cannot be opened up without risking too much damage to the lungs. Finally, if hypoventilation is present, output Yes in block 128, the PIP is again compared with the maximum PIP value in block 142 and the procedure continues as described. Thereby an opening pressure $P_o$ or the maximum allowed pressure will have to be found for all lung systems.

It should be noted that the opening pressure may also be found according to any other known procedure for finding an opening pressure, in particular those described in earlier Swedish patent applications Nos. 9502031-9 and 9502032-7. Another way of obtaining an opening pressure is described in SE-C-501 560.

As the opening pressure has been found, the second method proceeds with the reduction protocol, which corresponds to blocks 70 and 72 in FIG. 5. The first phase of the reduction protocol is to determine at which pressure the lungs will collapse again, i.e. the closing pressure $P_c$. In FIG. 11, a series of inspiration pulses 146A-146E is shown. These inspiration pulses 146A-146E correspond to the inspiration pulse sequence shown in FIG. 9, but with reducing values for PIP and PEEP. Thus the second inspiration pulse 146B has a lower PIP than the first inspiration pulse 146A and the third inspiration pulse 146C has an even lower PIP. For the fourth inspiration pulse 146D, both the PEEP and the PIP have been reduced and for the fourth and fifth inspiration pulses 146E and 146F, small changes in the PIP are made. The procedure for finding the closing pressure $P_c$ is described in the flow chart in FIG. 12 and commences with the start block 148.

Similar to the steps for finding the opening pressure $P_o$ the $P_aO_2$ is analysed in block 150 and thereafter a check is made whether the lung is open or not in block 152. In all further references to measuring of $P_aO_2$, it is assumed that any changes in the condition of the alveoli has had time to influence the $P_aO_2$. When the lungs are open no longer, the closing pressure $P_c$ has been determined and the procedure for finding the closing pressure will be ended in block 154. However, this will normally not be the case in the beginning of the procedure and the lungs would normally be open, output Yes block 152. It is then checked whether severe hypoventilation is present, block 156. If there is severe hypoventilation, output Yes, it is checked whether external PEEP exceeds a minimum external PEEP value, block 162. If external PEEP is lower than the minimum external PEEP value, output No, it is checked whether a new minima should be allowed, block 160. If not, the procedure ends in block 154. If a new minimum value is allowed, output Yes, the procedure resumes with the analysis of $P_aO_2$ in block 150. If external PEEP is higher than the minimum external PEEP value, output Yes, a new PEEP is set equal to the current PEEP - 2 $cmH_2O$, block 164 and the procedure resumes with the analyse of the $P_aO_2$ in block 150.

If the check for severe hypoventilation, block 156 results in a negative answer, output No, it is checked whether PIP exceeds the minimum PIP value in block 166. If the PIP is lower than the minimum PIP value, output No, the procedure continues by checking for hyperventilation, block 158. Hyperventilation is caused by unnecessary high ventilation of the alveoli and is indicated by a low carbon dioxide production. This can be measured either in the expired respiratory gas or by

analysing the partial pressure of carbon dioxide $P_aCO_2$ in the blood. If there is hyperventilation, output Yes, it will be necessary to check whether new minimum values should be allowed or not in block 160. Returning now to block 158 and the control for hyperventilation. If there is no hyperventilation, output No, PEEP is evaluated as described above in block 162.

However, if PIP is still above minimum, output Yes in block 166, the procedure continues in block 168 by checking whether the tidal volume $V_t$ is lower than 7 ml/kg (similar to the check in connection with FIG. 10). If the tidal volume $V_t$ is indeed lower than this $V_t$ threshold value, output Yes, the procedure continues by checking whether there is hypoventilation in block 170 and if so, output Yes, it will resume with block 162.

If any of the checkings in blocks 168 and 170 falls out negative, that is, if the tidal volume $V_t$ is above 7 ml/kg or if there is no hypoventilation, the current PIP is compared to a first PIP threshold value in block 172. In this case, the first PIP threshold value is 40 $cmH_2O$. If PIP is above the first PIP threshold value, which could very well be the case in the beginning of the closing pressure ($P_c$) procedure, a new PIP is set equal to the current PIP minus a first predefined decrement, e.g. 3 $cmH_2O$, block 174. After the new PIP has been set, the $P_aO_2$ is again analysed, block 150. Again, there should be a certain time lapse before the analysis is carried out to ascertain that any reactions in the lungs and blood system due to the lowered PIP has time to take place. If the current PIP is already below 40 $cmH_2O$, output No in block 172, the current PIP is compared with a second PIP threshold value in block 176. The second PIP threshold value is in this case 25 $cmH_2O$ and if the current PIP exceeds this second PIP threshold value, output Yes, a new PIP is set to be equal to the current PIP minus a second predefined decrement, e.g. 2 $cmH_2O$, block 178. As before, when a new value has been set the $P_aO_2$ is analysed in block 150. Should PIP be below even 25 $cmH_2O$, it will be is compared with a third PIP threshold value, block 180. The third PIP threshold is the programmed minimum PIP value, which could be e.g. 20 $cmH_2O$. Since PIP is normally a measured PIP value, it might at this stage be below the minimum PIP value, although it was above the minimum value in the control made in block 166. Should this occur, the procedure would resume at block 158, as was the case when the PIP was below the minimum PIP value in block 166. Normally, however, at this stage of the procedure, the current PIP will at least be above the minimum value, output Yes, and a new PIP is set to be equal to the current PIP minus a third predefined decrement, e.g. 1 $cmH_2O$, block 182. The procedure then resumes by analysing the $P_aO_2$ in block 150. This procedure, with subsequent lowering of the PIP and PEEP values, continues until the lungs are considered to have collapsed again. In other words, when the measured $P_aO_2$ falls below a predetermined $P_aO_2$ threshold value or displays a significant change between two $P_aO_2$ measurements which is above a certain defined level, the procedure will end.

It should be noted that changes in the blood gas parameter ($P_aO_2$) can also be used for determining new settings. For example, when determining opening and closing pressures, the change in measured $P_aO_2$ could be used for determining a new PIP or PEEP.

When the closing pressure $P_c$ has been found, the next phase, the steps of maintaining the lung open, can follow. This is shown in the flow chart in FIG. 13. The start is indicated in block 184 and the first thing to do is to set the determined opening and closing pressures ($P_o$ and $P_c$) sequentially, block 186. Since this procedure has the major task of maintaining the lungs open, this is checked in blocks 187 and 188 by analysing $P_aO_2$ and comparing it with the threshold value. Should there at any time be discovered that the lungs are not open, as reflected in the measured $P_aO_2$, a new opening pressure $P_o$ and closing pressure $P_c$ must be found, i.e. the procedures described in the flow charts of FIGS. 9 and 11 would be repeated in order to find these two important pressure values. As long as the lung remains open, output Yes, the maintenance procedure continues by checking for hyperventilation in block 192. If there is no hyperventilation present, output No, it is instead checked whether hypoventilation is present, block 194. As long as there is no hypoventilation, output No, the haemodynamics are checked in block 195. These controls, for hyperventilation in block 192, for hypoventilation in block 194 and for the haemodynamics in block 195 are all important parts in the main structure of the invention of ventilating the patient with the lowest pressures possible without impeding on the lung system or the blood system. If the haemodynamics are also OK, output Yes in block 195, the procedure is at an end in block 196. This procedure will then be repeated at predetermined intervals during the treatment of the patient in order to make sure that the patient' status is still stable.

Should there be hyperventilation present, output Yes in block 192, it has to be evaluated whether this depends on the respiratory rate, the PEEP pressure, the PIP, or if the dead space can be increased. This evaluation procedure is shown in a flow chart in FIG. 14.

This evaluation starts in block 206 and the first thing to do is to increase the respiratory rate by a factor of 1.2, block 208. Hyperventilation is then checked for, block 210, and if the increase in the respiratory rate was successful there will no longer be hyperventilation and the evaluation ends in block 212. If hyperventilation is still present, output Yes, it is checked whether the respiratory rate RR has already been increased twice, block 214. If not, respiratory rate is again increased by a factor of 1.2, block 208 and hyperventilation is checked for again. If the respiratory rate RR has been increased twice, output Yes in block 214, then the respiratory rate will not be further increased. Instead, it is checked whether PEEP is greater than the maximum PEEP value, block 216. If PEEP is lower than the maximum PEEP value, PEEP will be increased by 2 $cmH_2O$, block

218. It is then checked whether the increase in PEEP has had an effect on the hyperventilation, block 220. If there is no hyperventilation any longer, the evaluation ends, block 212, with the new settings for respiratory rate RR and PEEP. If, however, hyperventilation is still present, PEEP will be increased in steps of 2 $cmH_2O$ until it reaches the maximum PEEP value. If, during this time, hyperventilation has not ceased, the PIP will have to be decreased instead, block 222. PIP is decreased by 1 $cmH_2O$. After this decrease it is first checked whether the lungs are still open or not, block 224. If they are, it is checked whether the increase in PIP has been able to stop the hyperventilation, block 226. If there is no hyperventilation present, the evaluation has been successful and ends in block 212. If there is still hyperventilation, the dead space of the ventilation system is increased, block 228. Dead space is then increased until there is no hyperventilation present. After each increase in dead space, it is also checked whether the lungs are still sufficiently open, block 224. Should the measured $P_aO_2$ indicate that the lungs are not open any longer, they will have to be opened up again, block 230, and the maintenance procedure will then have to resume again, block 232. It should be noted that block 232, maintain the lung open, in FIG. 14 corresponds to the maintain lung open procedure described in FIG. 13.

If the dead space has to be increased, there are several ways of solving this. The immediate solution is of course to physically increase the dead space, especially by adding more tubing between the patient and the artificial ventilation system. However, this requires that the patient is disconnected from the artificial ventilation system and if he/she has not recovered sufficiently, this could cause the lungs to collapse. When the new tubing have been added, the entire procedure may thus have to be repeated by starting the evaluation scheme from the beginning. This is the main reason why it is checked whether the lungs are still open after each increase in dead space.

In FIG. 16 is shown a connecting system 6 for the artificial ventilation system. The connecting system 6 connects the respiratory gas driving unit 2 and the patient 4 to each other. The connecting system comprises a mixing chamber 254 in which the gases from respective gas inlet 2A, 2B, 2C are mixed into the respiratory gas. The mixed respiratory gas is lead via a inspiration tube 256 to a tracheal tube 258 or a corresponding connection tube to the patient. Expired respiratory gas is lead from the patient via the tracheal tube 258 and an expiration tube 260. On the tracheal tube 258 a section 262 consisting of a expandable-compressible material could be placed for affecting the dead space without disconnecting the patient. By expanding the section 262, the dead space will increase.

Another way of expanding the dead space is achieved by the use of a first valve 264 and a second valve 266. The first valve is located within the expiration tube 260 and may control the flow in the expiration tube 260. The second valve 266 is located in a connection between the inspiration tube and the expiration tube within the gas delivery unit 2. The second valve 266 is normally closed and the respiratory gas passes through the connection system 6 as described. However, by opening the second valve 266 and closing the first valve 264 during the last part of the expiration, expired gas will not be able to flow in the expiration tube 260, since this has been sealed off by the first valve 264. Instead the expired gas will flow into the inspiration tube 256 in the direction towards the opening between the inspiration tube 256 and expiration tube 260, i.e. the second valve 266. A part of the inspiration tube 256 will then act as an extension of the tracheal tube 258, or operate as an expansion of the section 262. As the next inspiration pulse is delivered the first valve 264 will open and the second valve 266 will close and the inspiration will commence as any other normal inspiration.

A further gas connection 268 is also included in the system. The further gas connection is connected to a controllable gas source and ends in the tracheal tube 258. The flow of gas within the further gas tube 268 can be controlled simultaneously with the respiratory gas flow, so that the total amount of gas supplied to the patient is controlled at a high degree. The further gas tube 268 could be used in a yet further way of increasing dead space, or rather, to obtain a similar effect. Instead of physically changing dead space, a small content of carbon dioxide could be added to the respiratory gas either directly through one of the gas inlets 2A, 2B, 2C or via the further gas tube 268. This addition of carbon dioxide could be operated so it supplies a small amount of carbon dioxide at the onset of inspiration, whereby it would simulate an increased dead space. The amount of added carbon dioxide could be calculated for each individual patient by comparing either with values measured when there was no hyperventilation or with the body weight or with other calculations.

When all the checkings, resulting from the detection of hyperventilation, have been made and evaluations have resulted in a new setting of any kind, the maintenance procedure in FIG. 13 resumes.

(Referring again to FIG. 13) Should there instead be hypoventilation present, output Yes in block 194, there is an evaluation made in block 200 whether the dead space is too large or whether there is a wrong peak inspiratory pressure PIP. This evaluation is shown in FIG. 15, which commences with the start block 234. First, it is checked whether the dead space exceeds the minimum value of the dead space, block 236. If the dead space exceeds the minimum value, the dead space is decreased, block 238. Thereafter it is again checked whether there is hypoventilation or not, block 240. If not, the evaluation is over, block 242. As long as there is hypoventilation and the dead space exceeds the minimum value, this sequence is repeated. If there is still hypoventilation when the dead space reaches the minimum value of the dead space, output No in block 236, it is checked whether the current PIP exceeds the maximum PIP allowed, block 244. If the current PIP

does not exceed the maximum PIP, the current PIP value is increased by 1 $cmH_2O$, block 246. As for the evaluation described for hyperventilation situations, PIP is then increased by 1 $cmH_2O$ until hypoventilation ceases, or the maximum PIP is reached. Again, the maximum PIP ensures that damaging pressures are avoided. Thus, hypoventilation is looked for, block 248. If the hypoventilation has ceased before the current PIP has reached the maximum PIP, the evaluation is at an end in block 242. If, however, hypoventilation persists, output Yes in block 246, and the current PIP has reached the maximum PIP, then hypoventilation has to be accepted for the time being and the evaluation comes to an end in block 242.

In similarity to the hyperventilation condition the dead space could easily be changed by physically removing some of the tubing which causes the hypoventilation to occur in the patient. Again this would mean that the entire procedure may have to be repeated, since the patient's lungs risk to collapse during the disconnection of the patient. Referring again to FIG. 16, the patient does not necessarily have to be disconnected. The expandable section 262 could be compressed in order to decrease the dead space. Another way of decreasing the dead space is to provide air at the end of the expiration phase via the further gas tube 268. Hereby the last expired volume will be mixed with a defined amount of air and as the inspiration phase commences the rebreathed amount of respiratory gas will be lower. If the dead space has been increased by utilizing the above described function (FIG. 16) of the first valve 264 and the second valve 266, the dead space may easily be decreased by going back to a normal inspiration/expiration timing, i.e. not utilize this function of the first valve 264 and second valve 266.

If the check for haemodynamics, block 195 in FIG. 13, should indicate that there is haemodynamic depression, it will be necessary to check if there is a pneumothorax, i.e. if air enters the pleural space in the lungs, block 201. Pneumothorax is in many cases caused by a penetration of the chest wall. In open pneumothorax the lung will collapse and not contribute to the ventilation. During artificial ventilation there is however a higher probability that there will be a closed pneumothorax. The closed pneumothorax is a rupture in the lung, causing a direct connection between the bronchial system and the pleural space. If there is a pneumothorax present, output Yes, the pressure must be relieved, block 202, e.g. by inserting a chest tube. The haemodynamics are preferably controlled by checking for cardiovascular depression based on the blood pressure measurements made by the monitoring unit. Other known measurements indication haemodynamic depression can, of course, also be used.

If there are cardiovascular depression but no pneumothorax, output No in block 201, or if a pneumothorax has been relieved at an earlier stage, an intravascular fluid challenge should be given, block 204. If the fluid challenge is successful more fluids should be given up to an allowed maximum volume. Thereafter cardiovascular active drugs should be given to the patient in order to overcome these distresses and negative side-effects for the patient. When all these measures have been taken, which a physician could indicate by queuing a certain code on the control panel or on the monitor screen in the artificial ventilator system the maintenance sequence is at an end in block 196.

At predetermined time intervals the control unit will run through the maintenance procedure.

When the patient has improved sufficiently, it is time for weaning him/her. The basic principle when weaning a patient is not to force the patient to breathe spontaneously immediately. Slowly at first, and then, when the patient takes a sufficient amount of spontaneous breaths, a more rapid transition from the controlled ventilation to support modes of ventilation.

In FIG. 17 this is described by a flow chart. The weaning protocol, or procedure, commences in block 270. As for the preceding protocols, the $P_aO_2$ is measured, block 272. The measured $P_aO_2$ is then compared with a first threshold T1, block 274. The first threshold T1 corresponds to a level of good oxygenation. It should be remembered that at this stage in the treatment of a patient, the lungs are open and the patient practically recovered from the condition which required the artificial ventilation.

Should the measured $P_aO_2$ be lower than the first threshold T1, output No, it is compared with a second threshold T2, block 276. The second threshold T2 corresponds to a level of oxygenation which is considered sufficient. If the measured $P_aO_2$ is equal to, or exceeds the second threshold T2, i.e. falls between the first threshold T1 and the second threshold T2, the current settings are maintained for the time being, and a new measurement of $P_aO_2$ is performed after a predetermined time lapse, in this case 10 minutes, block 278, and the procedure resumes with block 272.

Should the measured $P_aO_2$ be equal to, or exceed the first threshold T1 in block 274, the patients spontaneous respiration rate ($RR_s$) is measured and compared with a $RR_s$ threshold, block 280. The $RR_s$ threshold correlates to a sufficient spontaneous breathing, and if the measured spontaneous rate exceeds this threshold, output Yes, the weaning is at an end, block 282.

However, should the measured spontaneous respiratory rate be insufficient, or if the measured $P_aO_2$ is lower than the second threshold T2, an evaluation of the settings is made, block 284, before the procedure resumes again in block 272 - with new settings. Depending on whether the measured $P_aO_2$ was too low or the measured spontaneous respiratory rate was too low, the current settings of PIP, PEEP, RR and I:E ratio can be increased or decreased.

It should be noted that the figures used in the description for threshold values, as well as for minima and maxima, are purely given as examples. These figures could be different depending on, inter alia, the spe-

cies treated (human or animal), age (neonatal, infant, child, adult) and kind of illness. In the most straightforward realisation of the artificial ventilation system according to the invention, it could be adapted to automatically treat at least 90-99% of all adults, and require overriding settings from a physician in the remaining cases (before they too can be treated automatically).

## Claims

1. An Artificial ventilation system comprising a respiratory gas delivery unit (2), connectable to a lung system of a living being (4) for generating and delivering controllable inspiration pulses (78) of respiratory gas to the lung system, a regulating unit (8) connected to the respiratory gas delivery unit (2) for controlling the generation and delivery of inspiration pulses (78; 116A-116F; 146A-146F) based on a control signal supplied to the regulating unit (8), a monitoring unit (14, 14A-14F) for measuring at least one parameter related to the function of the lung system and a control unit (22) connected to the monitoring unit (14, 14A-14F) for determining a change in an inspiration pulse parameter, **characterized in** that the monitoring unit (14, 14A-14F) comprises a blood gas analyser (14A) connected to the blood system of the living being (4) for measuring a blood gas parameter and the control unit (22) determines an optimal peak inspiratory pressure (PIP) and pressure amplitude for the controllable inspiration pulse (78; 116A-116F; 146A-146F) based on the measured blood gas parameter, which optimal peak inspiratory pressure (PIP) and pressure amplitude are intended to provide a sufficient oxygenation of the blood system with a minimum of negative cardio-pulmonary influence, such as barotrauma, volutrauma, overdistension and hypoxic vasoconstriction.

2. Ventilation system according to claim 1, **characterized in** that the blood gas analyser (14A) measures the partial pressure of oxygen ($P_aO_2$) in the blood system and the control unit (22) determines a minimum peak inspiratory pressure (PIP) and pressure amplitude, for which the measured $P_aO_2$ exceeds a predetermined $P_aO_2$ threshold value.

3. Ventilation system according to claim 1 or 2, **characterized in** that the monitoring unit (14, 14A-14F) further comprises a flow meter (14B) for measuring the flow ($\Phi$) of respiratory gas to and/or from the lung system and the control unit (22) determines one or several of the inspiration pulse parameters: external positive end expiratory pressure ($PEEP_e$), respiration rate (RR) and inspiration/expiration time ratio (I:E ratio).

4. Ventilation system according to claim 3, **characterized in** that the control unit determines an end expiratory flow ($\Phi_{EE}$) and a peak expiratory flow ($\Phi_{PE}$) and determines an optimal respiration rate (RR) and/or an optimal inspiration/expiration time ratio (I:E ratio) based on the quotient between the determined end expiratory flow ($\Phi_{EE}$) and peak expiratory flow ($\Phi_{PE}$).

5. Ventilation system according to any of the above claims, **characterized by** a monitor screen (16, 18) connected to the monitoring unit (14, 14A-14F) for displaying measured parameters and/or connected to the control unit (22) for displaying determined inspiration pulse parameters.

6. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) generates the control signal based on the determined change in the inspiration pulse parameter.

7. Ventilation system according to any of the above claims, **characterized by** a control panel (10) connected to the regulating unit (8) for providing a further control signal based on a manually entered setting of ventilation modes and/or inspiration pulse parameters, whereby a further setting on the control panel (10) determines whether the control signal or the further control signal has precedence.

8. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) determines an opening pressure ($P_o$) of the lung system.

9. Ventilation system according to claim 8, **characterized in** that the control unit (22) determines a closing pressure ($P_c$) of the lung system.

10. Ventilation system according to any of the above claims, **characterized in** that the blood gas analyser (14A) measures the partial pressure of carbon dioxide ($P_aCO_2$) in the blood system.

11. Ventilation system according to any of the above claims, **characterized in** that the monitoring unit (14, 14A-14F) comprises a $CO_2$-meter (14E) for measuring the $CO_2$ content of expired respiratory gas and the control unit (22) determines any or several of the $CO_2$-parameters: end tidal $CO_2$, $CO_2$ minute production, $CO_2$ tidal production, ineffective tidal volume, effective tidal volume and effective ventilation.

12. Ventilation system according to claim 10 or 11, **characterized in** that the control unit (22) at predetermined intervals determines whether hypoventilation is present.

13. Ventilation system according to claim 12, **characterized in** that, when hypoventilation is present, the

control unit (22) determines a change in the peak inspiratory pressure (PIP) and/or the dead space (DS) of the artificial ventilation system for removing the hypoventilation condition.

14. Ventilation system according to any of the claims 10-13, **characterized in** that the control unit at predetermined intervals determines whether hyperventilation is present.

15. Ventilation system according to claim 14, **characterized in** that, when hyperventilation is present, the control unit determines a change in the peak inspiratory pressure (PIP) and/or the positive end expiratory pressure (PEEP) and/or the dead space (DS) of the artificial ventilation system and/or the respiratory rate for removing the hyperventilation condition.

16. Ventilation system according to any of the above claims, **characterized in** that the monitoring unit (14, 14A-14F) comprises a blood pressure meter (14D) for measuring a blood pressure of the blood system and the control unit (22) at predetermined intervals determines whether cardiovascular depression is present, and if cardiovascular depression is present, the control unit (22) will generate a cardiovascular depression signal, which cardiovascular depression signal preferably can be utilized for generating an audible/visual alarm and/or for controlling an inspiration pulse parameter.

17. Ventilation system according to any of the above claims, **characterized in** that the control unit (22) determines a new inspiration pulse parameter by iteratively changing the inspiration pulse parameter and monitoring the effect in the measured parameter(s) after a predetermined number of inspiration pulses, having the new inspiration pulse parameter, have been delivered to the lung system.

18. Method for controlling an artificial ventilation system, connectable to the lung system of a living being, **characterized by** the steps of:

a) determining an optimal ratio between inspiration time and expiration time (I:E ratio);
b) determining an optimal respiration rate (RR);
c) determining an opening pressure ($P_o$) of the lung system;
d) determining a closing pressure ($P_c$) of the lung system;
e) at intervals order a monitoring of the condition of the lung and, if necessary determine a change in an inspiration pulse delivered to the lung system;
f) ordering a change in the inspiration pulse for provoking spontaneous respiration.

19. Method according to claim 18, **characterized in** that step a) comprises the following sub-steps:

a1) reading a current I:E ratio;
a2) measuring an end expiratory flow ($\Phi_{EE}$);
a3) measuring a peak expiratory flow ($\Phi_{PE}$);
a4) calculating a EEPk$\Phi$-ratio between the measured end expiratory flow ($\Phi_{EE}$) and the peak expiratory flow ($\Phi_{PE}$);
a5) comparing the calculated EEPk$\Phi$-ratio with a predetermined first EEPk$\Phi$-threshold value;
a6) if the calculated EEPk$\Phi$-ratio exceeds the first EEPk$\Phi$-threshold value, determining the current I:E ratio as the optimal I:E ratio;
a7) if the calculated EEPk$\Phi$-ratio does not exceed the first EEPk$\Phi$-threshold value, comparing the current I:E ratio with a predetermined maximum I:E ratio;
a8) if the current I:E ratio exceeds the predetermined maximum I:E ratio, determining the current I:E ratio as the optimum I:E ratio;
a9) if the current I:E ratio does not exceed the predetermined maximum I:E ratio, comparing the current I:E ratio with a predetermined I:E ratio threshold;
a10) if the current I:E ratio exceeds the predetermined I:E ratio threshold, calculating a new I:E ratio, which is equal to the difference between the first EEPk$\Phi$-threshold value minus the calculated EEPk$\Phi$-ratio and the current I:E ratio and repeating the procedure from sub-step a1);
a11) if the current I:E ratio does not exceed the predetermined I:E ratio threshold, comparing the calculated EEPk$\Phi$-ratio ratio with a second EEPk$\Phi$-threshold value;
a12) if the calculated EEPk$\Phi$-ratio exceeds the second EEPk$\Phi$-threshold value, setting a new I:E ratio to be equal to the maximum I:E ratio and repeating the procedure from sub-step a1);
a13) if the calculated EEPk$\Phi$-ratio does not exceed the second EEPk$\Phi$-threshold value, determining the current I:E ratio as the optimum I:E ratio.

20. Method according to claim 19, **characterized in** that the first EEPk$\Phi$-threshold value is between 30 and 40, the second EEPk$\Phi$-threshold value is between 10 and 20 and the I:E ratio threshold is preferably between 60 and 80%.

21. Method according to any of the claims 18-20, **characterized in** that step b) comprises the following sub-steps:

b1) reading a current respiration rate (RR);
b2) measuring an end expiratory flow ($\Phi_{EE}$);
b3) measuring a peak expiratory flow ($\Phi_{PE}$);
b4) calculating a EEPk$\Phi$-ratio between the

measured end expiratory flow ($\Phi_{EE}$) and the peak expiratory flow ($\Phi_{PE}$);

b5) comparing the calculated EEPk$\Phi$-ratio with a predetermined first EEPk$\Phi$-threshold value;

b6) if the calculated EEPk$\Phi$-ratio exceeds the first EEPk$\Phi$-threshold value, determining the current respiration rate (RR) as the optimal respiration rate;

b7) if the calculated EEPk$\Phi$-ratio does not exceed the first EEPk$\Phi$-threshold value, comparing the current respiration rate (RR) with a predetermined maximum respiration rate;

b8) if the current respiration rate (RR) exceeds the predetermined maximum respiration rate, determining the current respiration rate (RR) as the optimum respiration rate;

b9) if the current respiration rate (RR) does not exceed the predetermined maximum respiration rate, comparing the calculated EEPk$\Phi$-ratio with a second EEPk$\Phi$-threshold value;

b10) if the calculated EEPk$\Phi$-ratio exceeds the second EEPk$\Phi$-threshold value, comparing the calculated EEPk$\Phi$-ratio with a third EEPk$\Phi$-threshold value;

b11) if the calculated EEPk$\Phi$-ratio exceeds the third EEPk$\Phi$-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a first factor and repeating the procedure from substep b1);

b12) if the calculated EEPk$\Phi$-ratio does not exceed the third EEPk$\Phi$-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a second factor and repeating the procedure from sub-step b1);

b13) if the calculated EEPk$\Phi$-ratio does not exceed the second EEPk$\Phi$-threshold value, determining a new respiration rate (RR) to be equal to the current respiration rate (RR) multiplied by a third factor and repeating the procedure from sub-step b1).

22. Method according to claim 21, **characterized in** that the first EEPk$\Phi$-threshold value is 40, the second EEPk$\Phi$-threshold value is 20, the third EEPk$\Phi$-threshold value is 30, the first factor is 1.2, the second factor is 1.5 and the third factor is 2.

23. Method according to any of the claims 18-22, **characterized in** that step c) comprises the following sub-steps:

c1) obtaining the lean body weight of the living being;

c2) delivering a predetermined number of inspiration pulses having a current peak inspiratory pressure (PIP) and a current positive end expiratory pressure (PEEP);

c3) measuring the partial pressure of oxygen ($P_aO_2$) in a blood system of the living being;

c4) comparing the measured $P_aO_2$ with a predetermined $P_aO_2$ threshold value;

c5) if the measured $P_aO_2$ exceeds the predetermined $P_aO_2$ threshold value, determining the PIP as the opening pressure ($P_o$) and storing the determined opening pressure ($P_o$) and current PEEP;

c6) if the measured $P_aO_2$ does not exceed the predetermined $P_aO_2$ threshold value, measuring an inspiration flow ($\Phi$) to the living being, determining a tidal volume ($V_t$) of supplied respiratory gas, calculating a quotient between the determined tidal volume ($V_t$) and the lean body weight and comparing calculated quotient with a predetermined $V_t$ threshold value;

c7) if the calculated quotient exceeds the predetermined $V_t$ threshold value, measuring a carbon dioxide content ($CO_2$ content) and comparing the measured CO2 content with a predetermined CO2 content threshold value;

c8) if the calculated quotient does not exceed the predetermined $V_t$ threshold value or if the measured CO2 content exceeds the predetermined CO2 content threshold value, comparing the current PIP with a predetermined maximum PIP value;

c9) if the current PIP does not exceed the maximum PIP value, setting a new current PIP to be equal to the current PIP plus a first predetermined increment and repeating the procedure from substep c2);

c10) if the measured CO2 content does not exceed the predetermined CO2 content threshold value, measuring the intrinsic positive end expiratory pressure ($PEEP_i$) and comparing it with a predetermined maximum $PEEP_i$ value;

c11) if the measured $PEEP_i$ does not exceed the predetermined maximum $PEEP_i$ value, comparing the current PIP with the maximum PIP value;

c12) if the current PIP does not exceed the predetermined maximum PIP value, setting a new current PIP to be equal to the current PIP plus a second predetermined increment, setting a new current PEEP to be equal to the current PEEP plus a third predetermined increment and repeating the procedure from substep c2);

c13) if the current PIP exceeds the predetermined maximum PIP value, comparing the current PEEP with a predetermined maximum PEEP value;

c14) if the current PEEP does not exceed the predetermined maximum PEEP value, setting a new current PEEP to be equal to the current PEEP plus a fourth predetermined increment and repeating the procedure from substep c2);

c15) if the current PEEP exceeds the predeter-

mined maximum PEEP value, or if the $PEEP_i$ in substep c10) exceeds the predetermined maximum $PEEP_i$ value, or if the current PIP in substep c8) exceeds the predetermined maximum PIP value, determining whether a new maximum PIP value, a new maximum $PEEP_e$ value or a new maximum $PEEP_i$ value should be allowed;

c16) if new maxima are not allowed, determining the current PIP as the opening pressure ($P_o$) and storing the determined opening pressure ($P_o$) and current PEEP;

c16) if new maxima are allowed, setting these and repeating the procedure from substep c2).

24. Method according to claim 23, **characterized in** that the predetermined $V_t$ threshold value is preferably between 5 and 7 ml/kg, the first predetermined increment is 2 $cmH_2O$, the second predetermined increment is 2 $cmH_2O$, the third predetermined increment is 2 $cmH_2O$ and the fourth predetermined increment is 2 $cmH_2O$.

25. Method according to any of the claims 18-24, **characterized in** that step d) comprises the following sub-steps:

d1) delivering a predetermined number of inspiration pulses having a current peak inspiratory pressure (PIP) and a current positive end expiratory pressure (PEEP);

d2) measuring pressure in or near the lung system, respiratory gas flow, partial pressure of oxygen ($P_aO_2$) in the blood system and a CO2 content, either in expired air or in the blood system;

d3) comparing the measured $P_aO_2$ with a predetermined $P_aO_2$ threshold value;

d4) if the measured $P_aO_2$ does not exceed the predetermined $P_aO_2$ threshold value, determining the current PIP as the closing pressure ($P_c$) and storing the determined closing pressure ($P_c$) and current PEEP;

d5) if the measured $P_aO_2$ does not exceed the $P_aO_2$ threshold value, comparing the CO2 content is compared with a first predetermined $CO_2$ content threshold value;

d6) if the $CO_2$ content exceeds the first predetermined $CO_2$ content threshold value, comparing the current PIP with a predetermined minimum PIP value;

d7) if the current PIP exceeds the predetermined minimum PIP value, determining the tidal volume ($V_t$) and comparing it with a predetermined $V_t$ threshold value;

d8) if the determined tidal volume ($V_t$) does not exceed the predetermined $V_t$ threshold value, comparing the $CO_2$ content with a second predetermined $CO_2$ content threshold value;

d9) if the determined tidal volume ($V_t$) exceeds the predetermined $V_t$ threshold value or if the $CO_2$ content does not exceed the second predetermined $CO_2$ threshold value, comparing the current PIP with a first PIP threshold value;

d10) if the current PIP exceeds the first PIP threshold value, setting a new current PIP to be equal to the current PIP minus a first predetermined decrement and repeating the procedure from substep d1);

d11) if the current PIP does not exceed the first PIP threshold value, comparing the current PIP with a second PIP threshold value;

d12) if the current PIP exceeds the second predetermined PIP threshold value, setting a new current PIP to be equal to the current PIP minus a second predetermined decrement and repeating the procedure from substep d1);

d13) if the current PIP does not exceed the second predetermined PIP threshold value, comparing the current PIP with a predetermined minimum PIP value;

d14) if the current PIP exceeds the predetermined minimum PIP value, setting a new current PIP to be equal to the current PIP minus a third predetermined decrement and repeating the procedure from substep d1);

d15) if the current PIP does not exceed the predetermined minimum PIP value, or if the $CO_2$ content in substep d5) exceeds the first predetermined $CO_2$ threshold value, or if the current PIP in substep d6) does not exceed the predetermined minimum PIP value, or if the $CO_2$ content exceeds the second predetermined $CO_2$ threshold value, comparing the $CO_2$ content with a third threshold value;

d16) if the $CO_2$ content exceeds the third $CO_2$ threshold value, comparing the current PEEP with a predetermined minimum PEEP value;

d17) if the current PEEP exceeds the predetermined minimum PEEP value, setting a new current PEEP to be equal to the current PEEP minus a fourth decrement and repeating the procedure from substep d1);

d18) if the current PEEP does not exceed the predetermined minimum PEEP value or if the $CO_2$ content does not exceed the third $CO_2$ content threshold value, determining whether a new minimum PIP value, or a new minimum PEEP value can be allowed;

d19) if new minimum values are allowed, setting the new minimum values and repeating the procedure from substep d1);

d20) if new minimum values are not allowed, determining the current PIP as the closing pressure ($P_c$) and storing the determined closing pressure ($P_c$) and current PEEP.

26. Method according to claim 25, **characterized in**

that the predetermined $V_t$ threshold value is preferably between 5 and 7 ml/kg, the first predetermined PIP threshold value is preferably between 30 and 45 $cmH_2O$, the second predetermined PIP threshold value is preferably between 20 and 30 $cmH_2O$, the first predetermined decrement is 3 $cmH_2O$, the second predetermined decrement is 2 $cmH_2O$, the third predetermined decrement is 1 $cmH_2O$ and the fourth predetermined decrement is 2 $cmH_2O$.

27. Method according to any of the claims 18-26, characterized in that step e) comprises the following sub-steps:

e1) measuring pressure, $CO_2$ content, $P_aO_2$ and blood pressure;
e2) comparing measured $P_aO_2$ with a predetermined $P_aO_2$ threshold;
e3) if the measured $P_aO_2$ does not exceed the predetermined $P_aO_2$ threshold value, repeating steps c) and d);
e4) if the measured $P_aO_2$ exceeds the $P_aO_2$ threshold, comparing the $CO_2$ content with a first predetermined $CO_2$ threshold value;
e5) if the $CO_2$ content exceeds the first predetermined $CO_2$ threshold value, altering the settings for respiratory rate (RR), positive end expiratory pressure (PEEP), peak inspiratory pressure (PIP) and/or dead space (DS) until the measured $CO_2$ content no longer exceeds the first predetermined $CO_2$ threshold value;
e6) if the $CO_2$ content does not exceed the first predetermined $CO_2$ threshold value, comparing the $CO_2$ content with a second predetermined $CO_2$ threshold value;
e7) if the $CO_2$ content exceeds the second predetermined $CO_2$ threshold value, altering the settings of dead space (DS) and/or peak inspiratory pressure (PIP) until the $CO_2$ content does not exceed the second predetermined $CO_2$ threshold value or until maximum/minimum values for dead space and PIP are reached;
e8) if the $CO_2$ content does not exceed the second predetermined $CO_2$ threshold value, comparing the blood pressure with a predetermined blood pressure interval;
e9) if the measured blood pressure falls within the predetermined blood pressure interval, ending step e);
e10) if the blood pressure falls outside the predetermined blood pressure interval, generating an alarm.

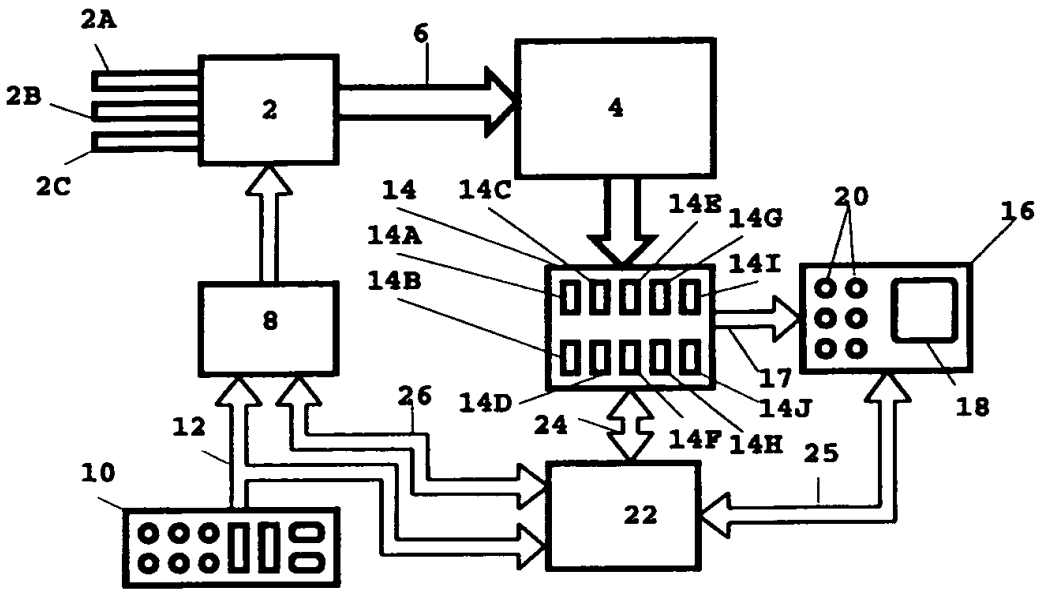
2A
2B
2C
2
6
4
14
14C
14E
14G
14A
14I
14B
20
16
8
17
18
26
14D
14J
12
24
14F
14H
25
10
22

FIG 1

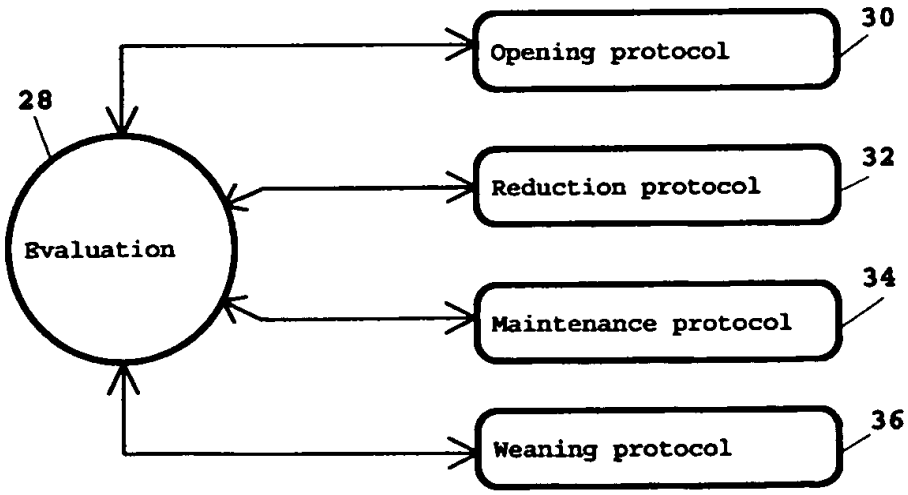
28
Evaluation
Opening protocol
30
Reduction protocol
32
Maintenance protocol
34
Weaning protocol
36

FIG 2

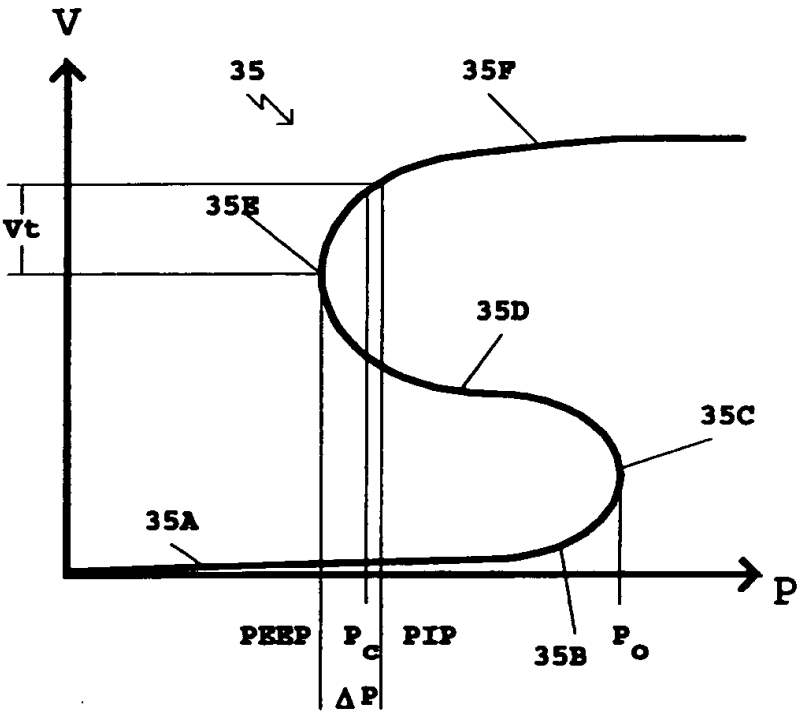


FIG 3

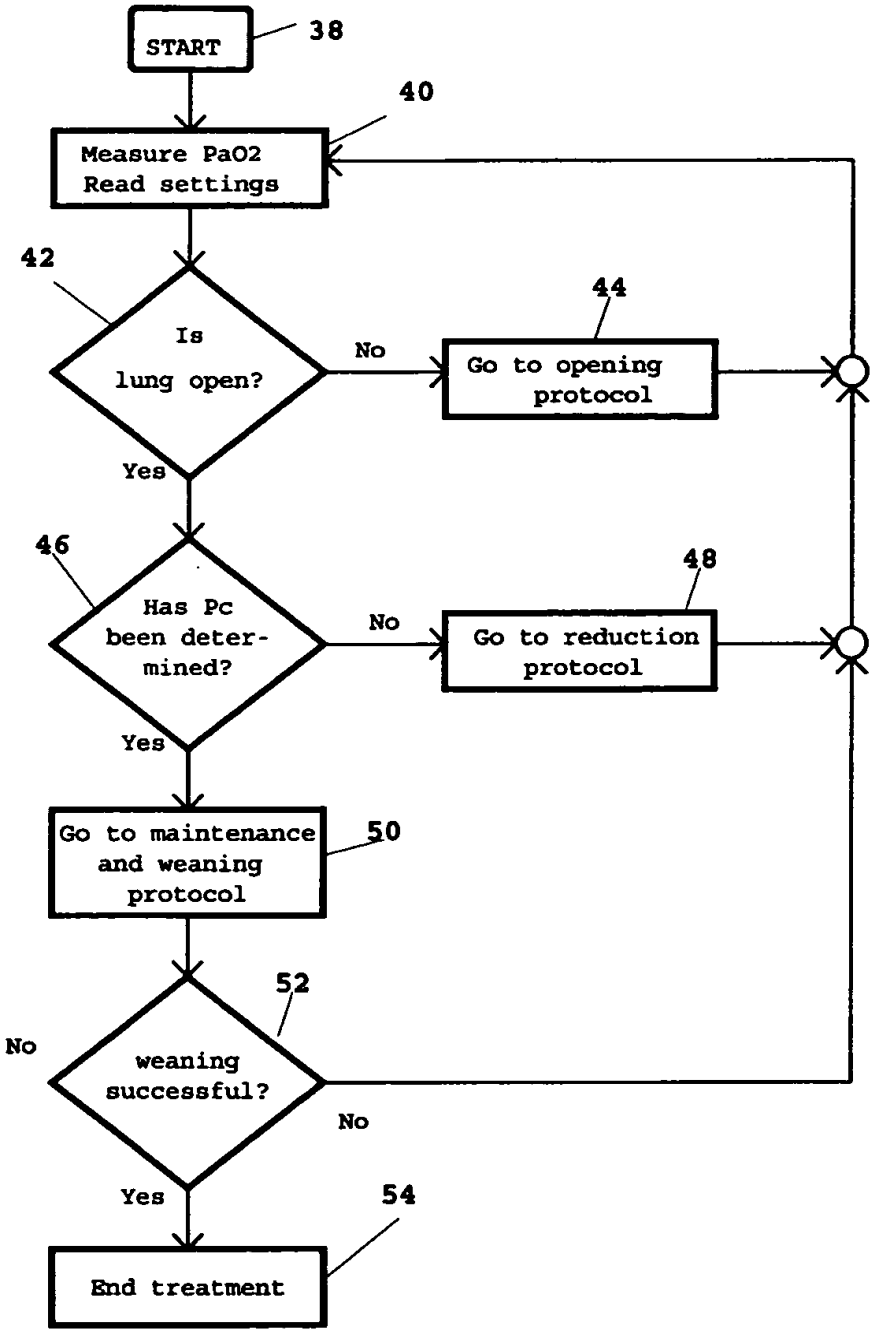
START
38
40
Measure PaO2
Read settings
42
Is
lung open?
No
44
Go to opening
protocol
Yes
46
Has Pc
been deter-
mined?
No
48
Go to reduction
protocol
Yes
Go to maintenance
and weaning
protocol
50
52
No
weaning
successful?
No
Yes
54
End treatment

FIG 4

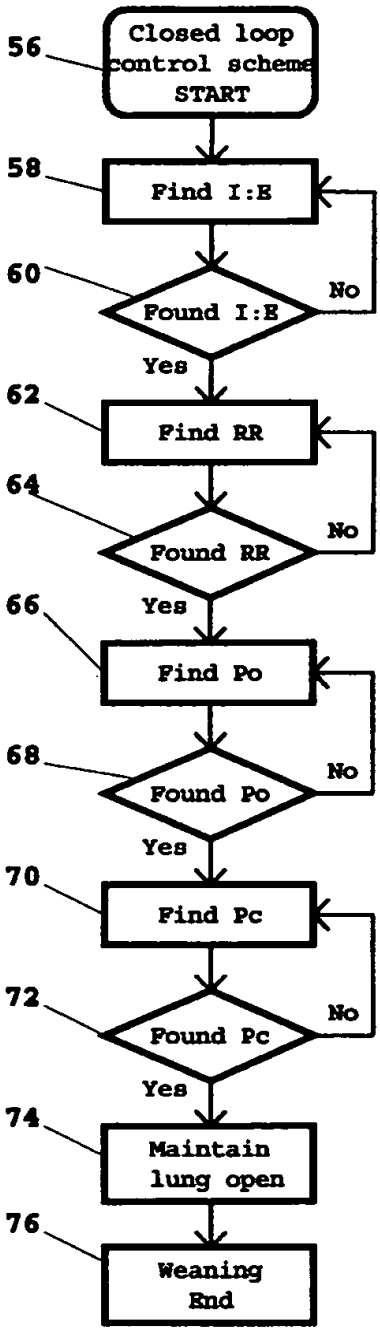
56
Closed loop control scheme START
58
Find I:E
60
Found I:E
No
Yes
62
Find RR
64
Found RR
No
Yes
66
Find Po
68
Found Po
No
Yes
70
Find Pc
72
Found Pc
No
Yes
74
Maintain lung open
76
Weaning End

FIG 5

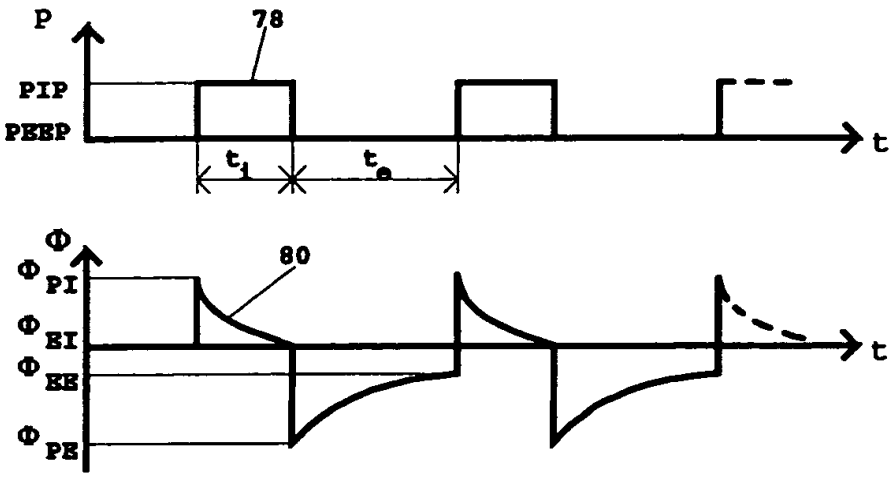
P
78
PIP
PEEP
t
$t_i$
$t_e$
Φ
80
$\Phi_{PI}$
$\Phi_{EI}$
$\Phi_{EE}$
$\Phi_{PE}$
t

FIG 6

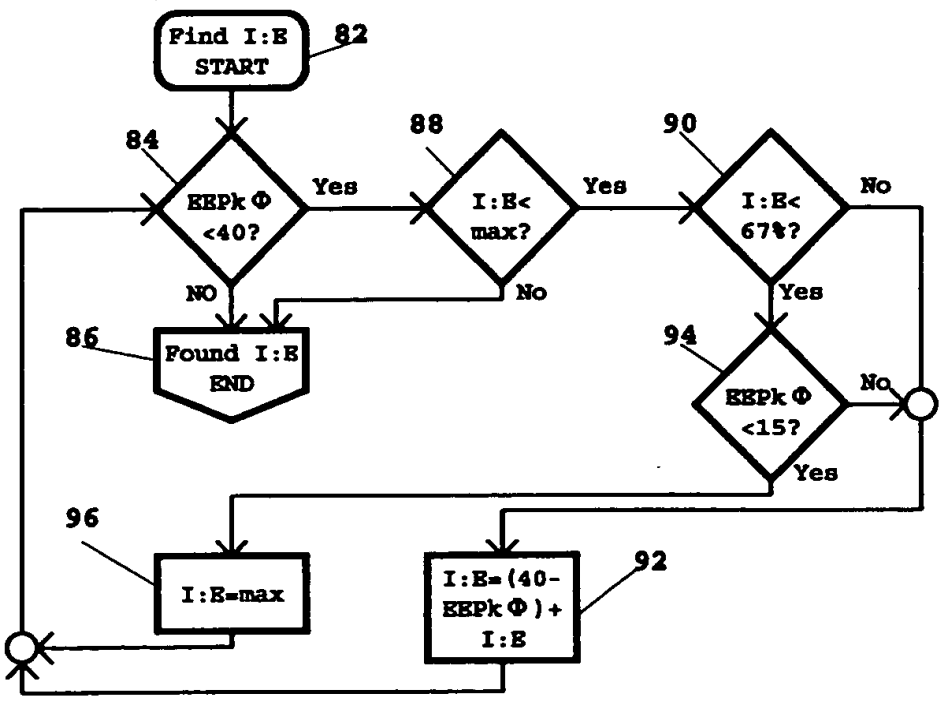
Find I:E START
82
84
EEPk Φ <40?
Yes
88
I:E< max?
Yes
90
I:E< 67%?
No
NO
No
Yes
86
Found I:E END
94
EEPk Φ <15?
No
Yes
96
I:E=max
I:E=(40-EEPk Φ)+ I:E
92

FIG 7

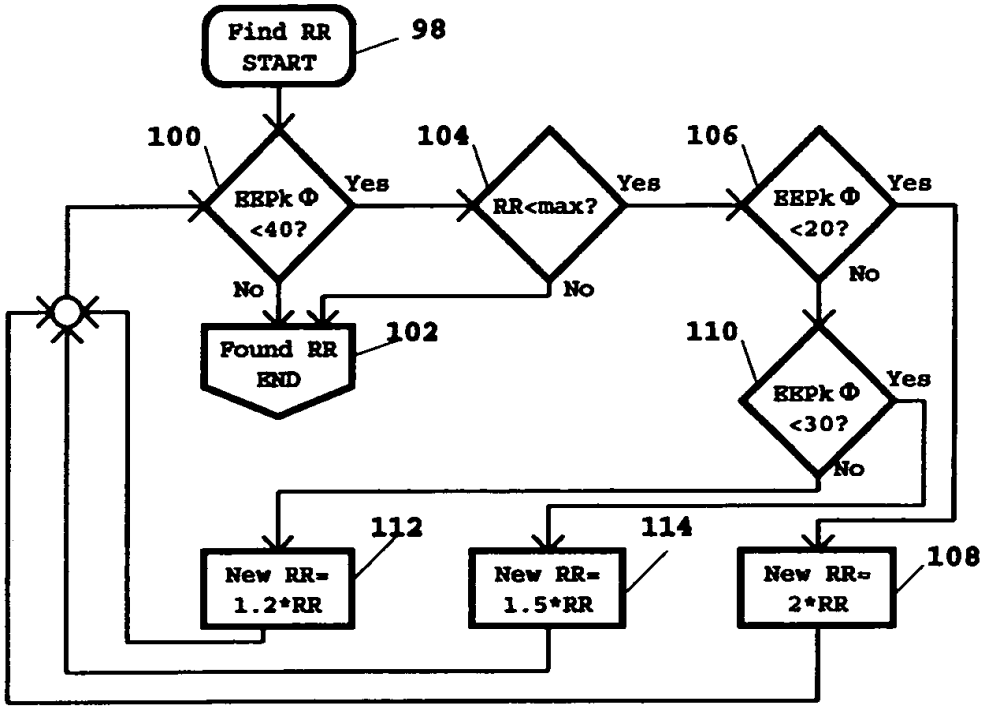
Find RR START
98
100
EEPk Φ <40?
Yes
No
104
RR<max?
Yes
No
106
EEPk Φ <20?
Yes
No
Found RR END
102
110
EEPk Φ <30?
Yes
No
112
New RR= 1.2*RR
114
New RR= 1.5*RR
108
New RR= 2*RR

FIG 8

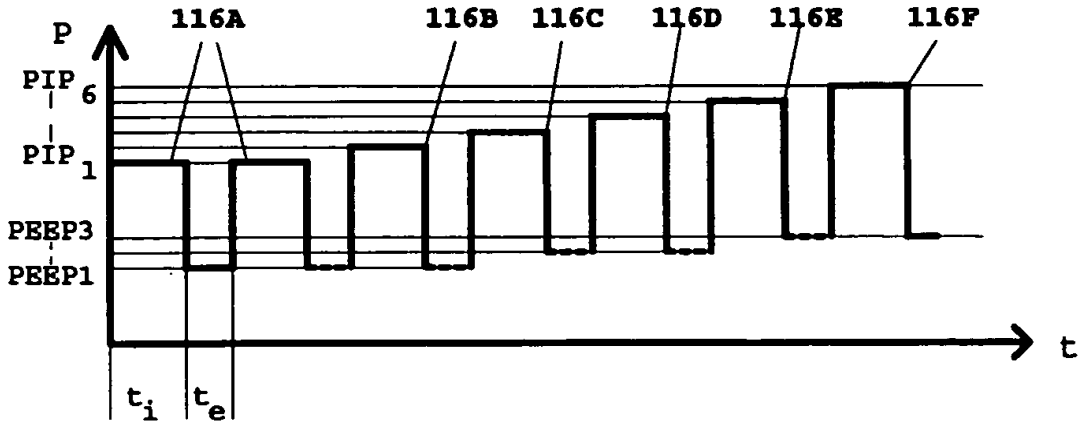
P
116A
116B
116C
116D
116E
116F
PIP 6
PIP 1
PEEP3
PEEP1
t
$t_i$
$t_e$

FIG 9

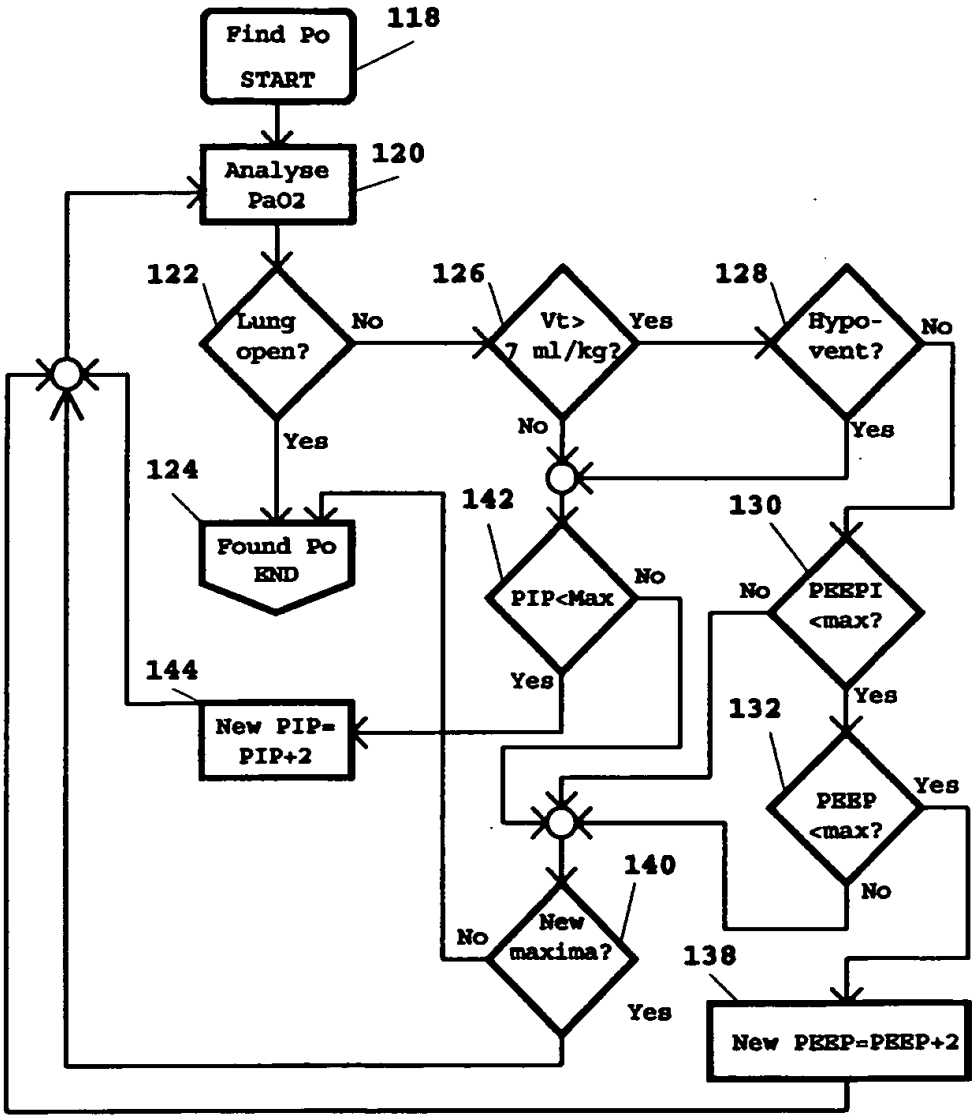
Find Po
START
118
Analyse
PaO2
120
122
Lung
open?
No
Yes
126
Vt>
7 ml/kg?
Yes
No
128
Hypo-
vent?
No
Yes
124
Found Po
END
142
PIP<Max
No
Yes
130
PEEPI
<max?
No
Yes
144
New PIP=
PIP+2
132
PEEP
<max?
Yes
No
140
New
maxima?
No
Yes
138
New PEEP=PEEP+2

FIG 10

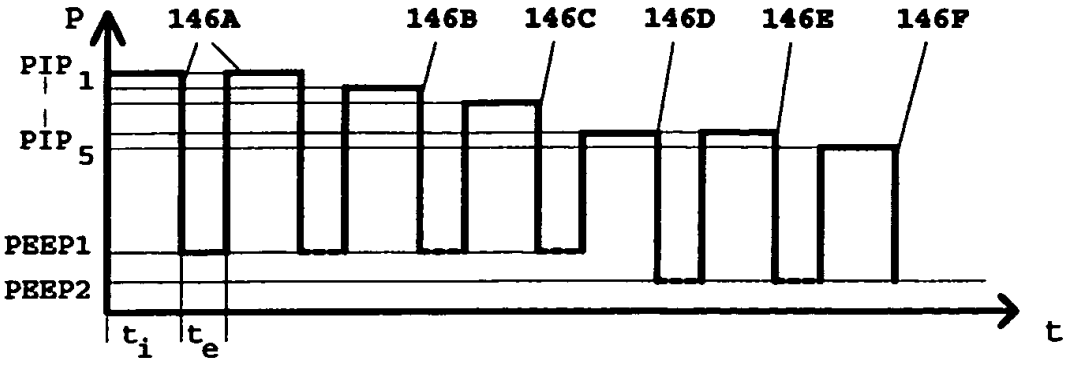
P
146A
146B
146C
146D
146E
146F
PIP 1
PIP 5
PEEP1
PEEP2
t
$t_i$
$t_e$

FIG 11

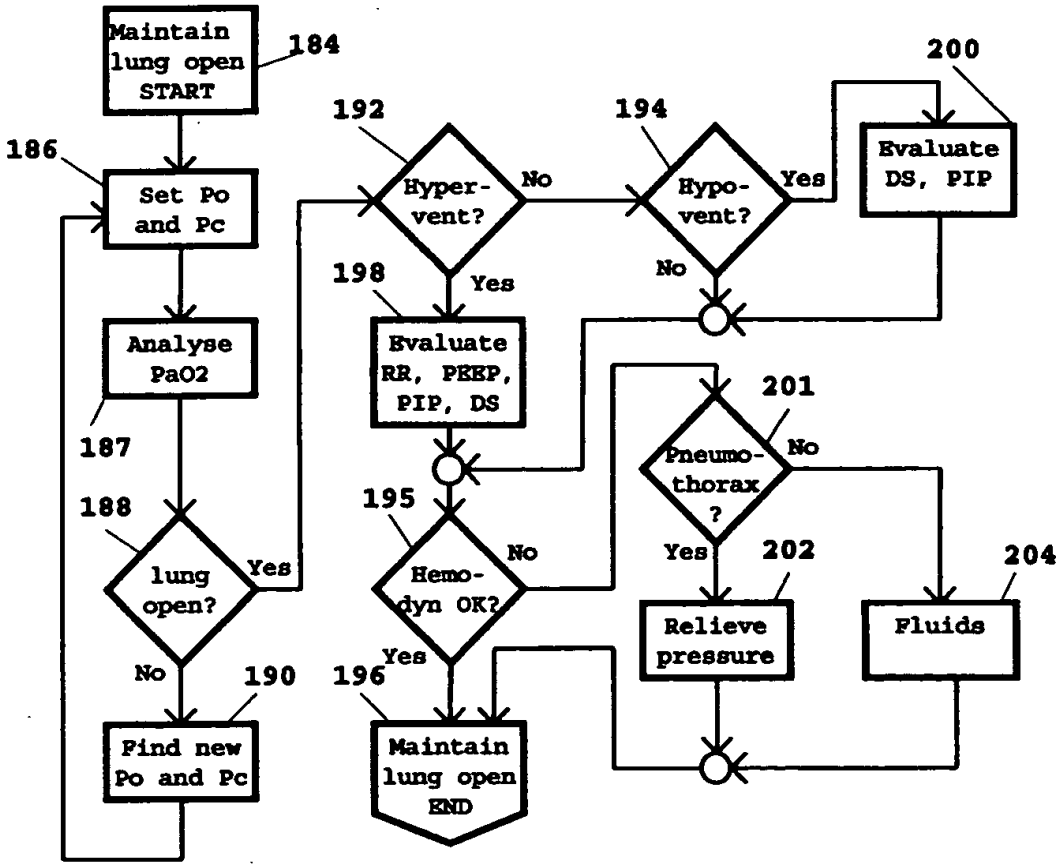
Maintain lung open START
184
186
Set Po and Pc
Analyse PaO2
187
188
lung open?
Yes
No
190
Find new Po and Pc
192
Hyper-vent?
No
Yes
194
Hypo-vent?
Yes
No
200
Evaluate DS, PIP
198
Evaluate RR, PEEP, PIP, DS
195
Hemo-dyn OK?
No
Yes
196
Maintain lung open END
201
Pneumo-thorax ?
No
Yes
202
Relieve pressure
204
Fluids

FIG 13

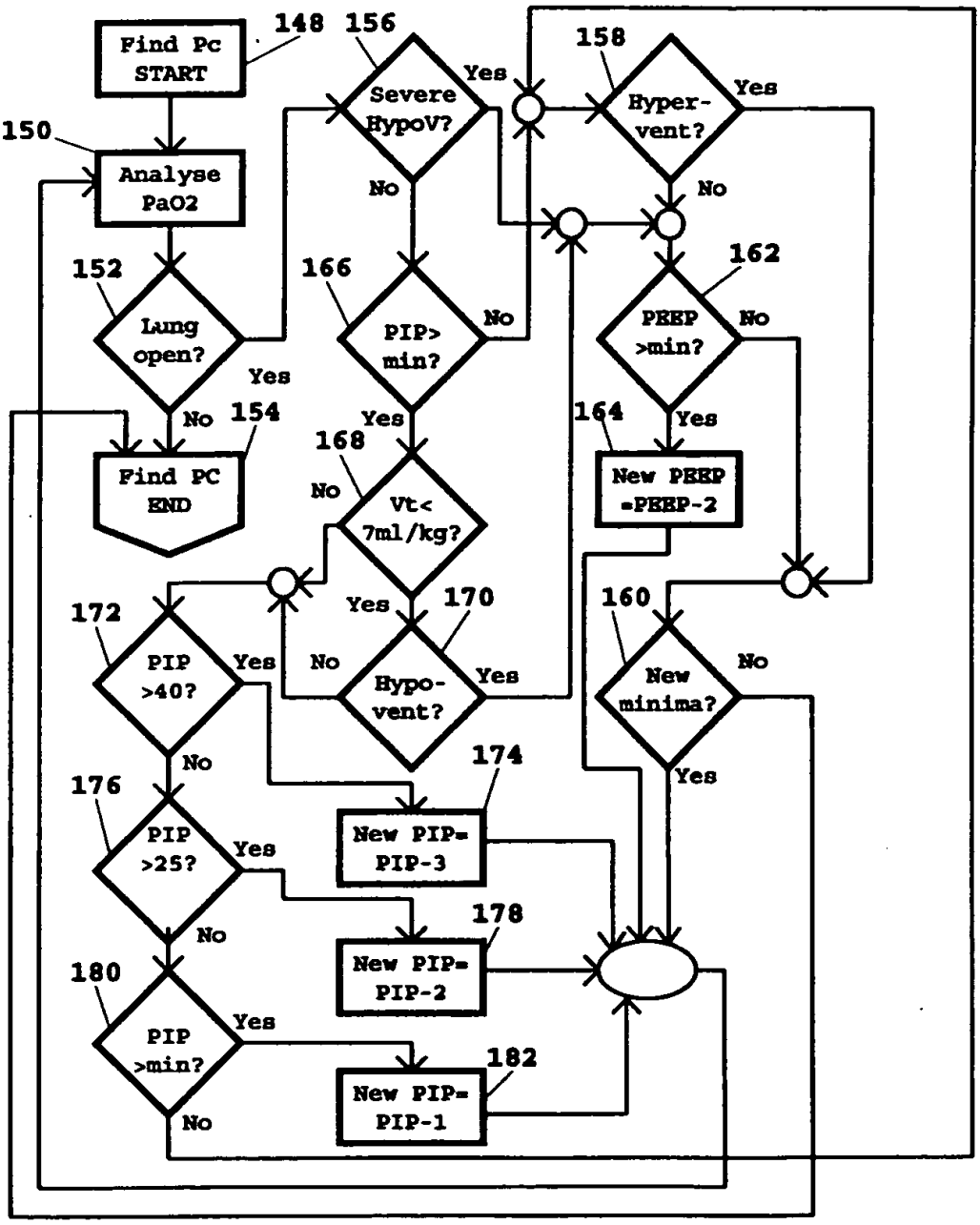
Find Pc START
148
156
Severe HypoV?
Yes
158
Hyper-vent?
Yes
150
Analyse PaO2
No
No
152
Lung open?
166
PIP> min?
No
162
PEEP >min?
No
Yes
Yes
No
154
Yes
164
Find PC END
168
New PEEP =PEEP-2
No
Vt< 7ml/kg?
Yes
170
160
172
PIP >40?
Yes
No
Hypo-vent?
Yes
New minima?
No
No
174
Yes
176
PIP >25?
Yes
New PIP= PIP-3
178
No
New PIP= PIP-2
180
PIP >min?
Yes
182
New PIP= PIP-1
No

FIG 12

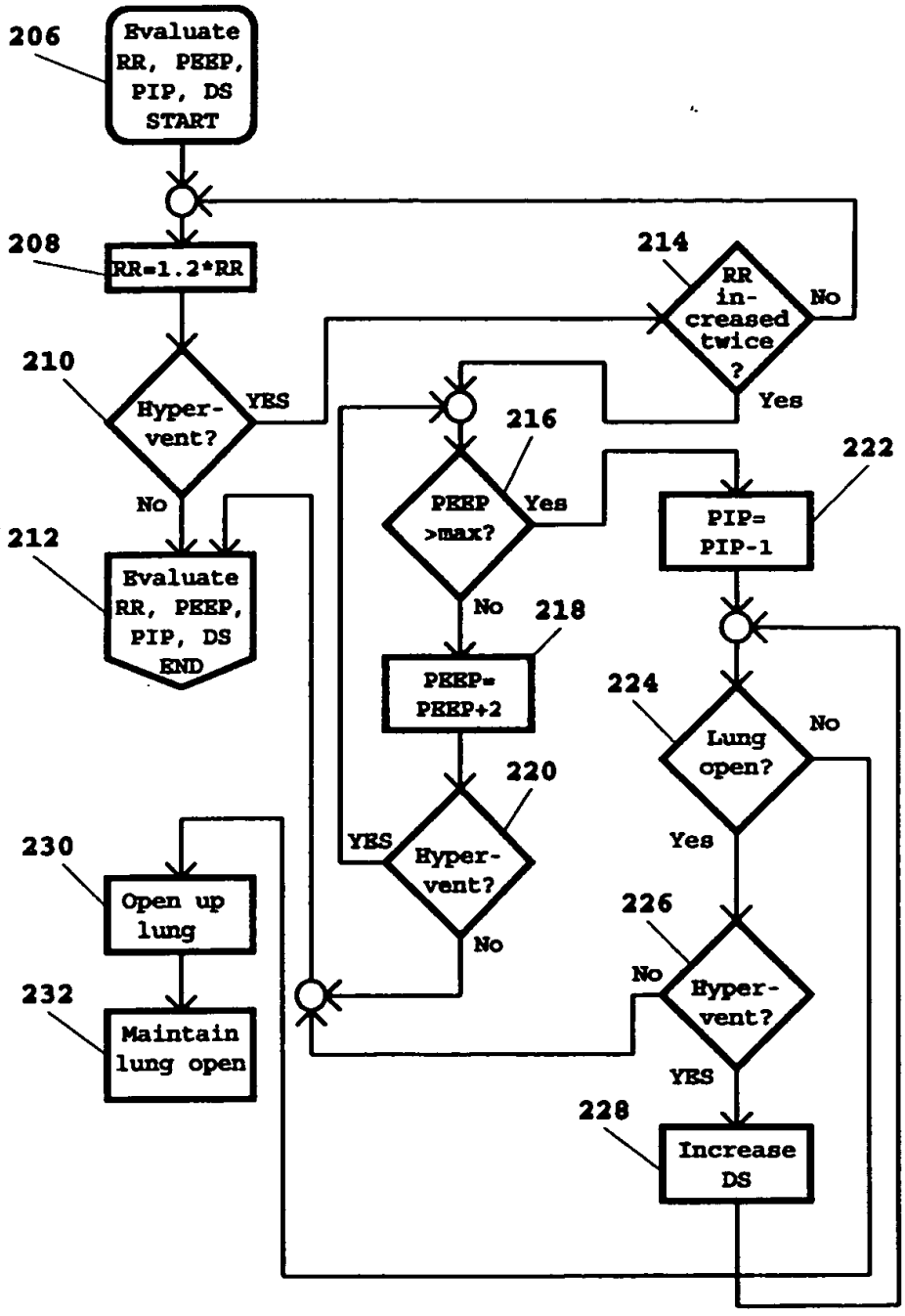
206
Evaluate RR, PEEP, PIP, DS START
208
RR=1.2*RR
210
Hyper-vent?
YES
No
212
Evaluate RR, PEEP, PIP, DS END
214
RR in-creased twice ?
No
Yes
216
PEEP >max?
Yes
No
218
PEEP= PEEP+2
220
Hyper-vent?
YES
No
222
PIP= PIP-1
224
Lung open?
No
Yes
226
Hyper-vent?
No
YES
228
Increase DS
230
Open up lung
232
Maintain lung open

FIG 14

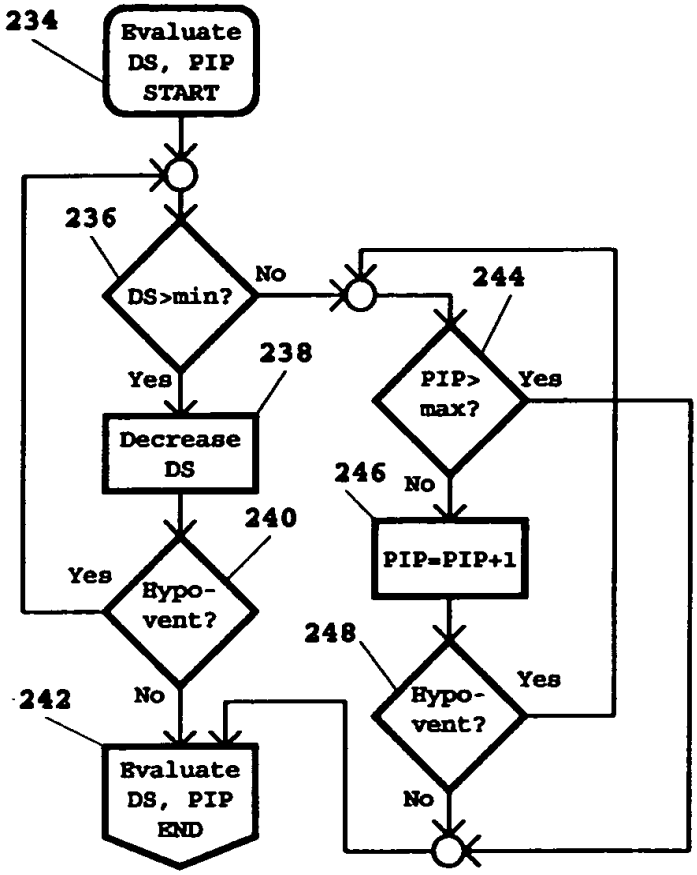
234
Evaluate DS, PIP START
236
DS>min?
No
Yes
238
Decrease DS
240
Hypo-vent?
Yes
No
242
Evaluate DS, PIP END
244
PIP> max?
Yes
246
No
PIP=PIP+1
248
Hypo-vent?
Yes
No

FIG 15

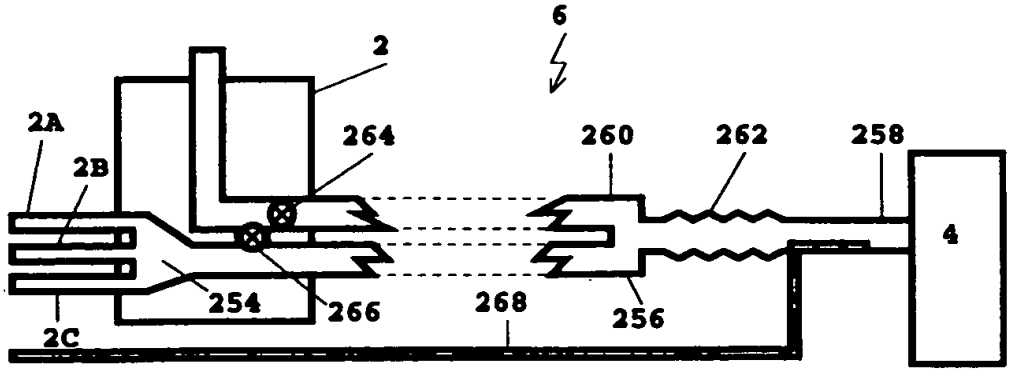
6
2
2A
2B
264
260
262
258
4
254
266
268
256
2C

FIG 16

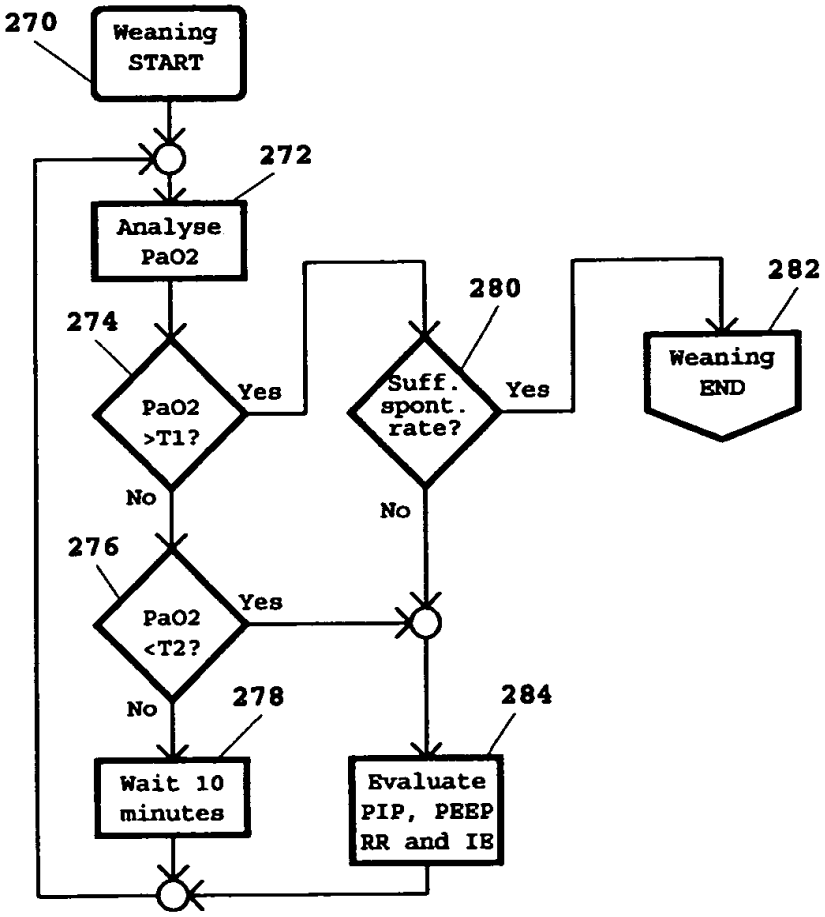
270
Weaning START
272
Analyse PaO2
274
PaO2 >T1?
Yes
No
276
PaO2 <T2?
Yes
No
278
Wait 10 minutes
280
Suff. spont. rate?
Yes
No
282
Weaning END
284
Evaluate PIP, PEEP RR and IE

FIG 17

European Patent Office

# EUROPEAN SEARCH REPORT

Application Number
EP 96 10 9790.4
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## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int. Cl.6) |
|---|---|---|---|
| A | US, A, 4986268 (FLEUR T. TEHRANI), 22 January 1991 (22.01.91) -- | 1-27 | A61M 16/00 |
| A | US, A, 5103814 (TIMOTHY MAHER), 14 April 1992 (14.04.92) -- | 1-27 | |
| A | US, A, 5365922 (DANIEL B. RAEMER), 22 November 1994 (22.11.94) -- | 1-27 | |
| A | US, A, 5388575 (JOHN C. TAUBE), 14 February 1995 (14.02.95) ----- | 1-27 | |

TECHNICAL FIELDS SEARCHED (Int. Cl.6)

A61M

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| STOCKHOLM | 27 September 1996 | JACK HEDLUND |

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